


HDI 5000

Ultrasound System

Scanheads and Safety

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United States federal law restricts this device to sale by or on the order of a physician.

CE 0086

ATL Ultrasound products may be manufactured under or operate in accordance with one or more of the following United States patents and corresponding patents in other countries: U.S. Patent Numbers 4,581,636; 4,607,642; 4,543,960; 4,644,795; 4,887,306; 5,016,641; 5,123,415; 5,197,477; 5,255,682; 5,050,610; 5,226,422; 5,275,167; 5,207,225; 5,287,753; 5,215,094; 5,381,795; 5,386,830; 5,402,793; 5,390,674; 5,438,994; 5,471,989; 5,482,045; 5,476,097; 5,471,990; 5,456,257; 5,485,842; 5,482,047; 5,479,930; Re 35,148; 5,555,887; 5,617,863; 5,669,385; 5,645,066; D369,307; 5,634,465; 5,603,323; 5,706,819; 5,715,823; 5,718,229; 5,720,291; 5,879,303, 5,951,478; Re 36,564; 5,980,457; 5,961,462; 5,940,123; 5,908,389; 5,891,035; 5,860,924; 5,795,297; 5,846,200; 5,833,613. Other patent applications are pending in various countries.


Read This First

About Your Manual Set

This manual is part of a manual set. The manual set addresses the reader who is familiar with ultrasound techniques. Sonography training and clinical procedures are not included in the manual set. The manual set includes the following:

- ***Getting Started*****:** Introduces you to basic system features and concepts. When you complete the procedures in this manual, you will know how to use these features and understand the concepts of system operation.
- ***Scanheads and Safety*****:** Contains information about safety, scanheads, biopsy guides, transesophageal and laparoscopic scanheads, and acoustic output.
- ***Reference Manual*****:** Contains information that supports and amplifies the procedures in *Getting Started*. It includes image management, maintenance, troubleshooting, specifications, references, and a glossary.
- ***Using Disinfectants and Gels*****:** Contains information about compatible gels and disinfectants and disinfecting ATL products.
- ***Acoustic Output Tables:*** Contains information about mechanical and thermal index precision and accuracy, the acoustic output default tables, and the acoustic output tables.
- ***Medical Ultrasound Safety:*** Contains information about bioeffects and biophysics, prudent use, and implementing ALARA (as low as reasonably achievable).
- ***Operating Notes*****:** Contains information that clarifies certain system responses that might be misunderstood or cause user difficulty.

About Your Manual Set on Compact Disc (CD)

A CD is included in a pocket on the inside back cover of the *Getting Started* manual. The CD contains the complete manual set, except for the *Operating Notes.* The instructions for using the CD are on the last page of the *Getting Started* manual.

Please take the time to use the CD, complete the brief survey card included with the manual set, and mail the survey card to us.

Conventions Used in This Manual

These conventions are used in this manual:

- All procedures are numbered. You must complete steps in the sequence they are presented to ensure a reliable result.
- Bulleted lists indicate general information about a particular function or procedure. They do not imply a sequential procedure.
- Control names appear in this manual like they appear on the system.
- Menu items or titles appearing on the display are shown in the manual like they appear on the display.
- The left side of the system is to your left as you stand in front of the system, facing the system.
- Scanheads and pencil probes both are referred to as scanheads, unless the distinction is important to the meaning of the text.
- “Select” means to place the cursor over an item and press **SELECT** once.
- “Double-select” means to place the cursor over an item, and quickly press **SELECT** two times, like double-clicking with a computer mouse. Pressing **SELECT** too slowly on double select will only highlight an item. Pressing it rapidly will initiate an action.

System Conventions

These conventions are used in the system:

- The software that runs the system uses graphic display elements similar to those used in many personal computers. References to these elements in the software or in the manual are defined in the glossary in the *Reference Manual*.
- On a menu, protocol, or other display, a highlight bar indicates that the item or name contained within the boundaries of the highlight bar is in the process of being selected. Pressing the **SELECT** control or other related control actually selects the item, assigns a value to a system parameter, or initiates the action related to the selected item.
- On a menu, an underlined letter indicates that pressing the underlined letter on the system keyboard will have the same effect as selecting the menu item with the trackball and the **SELECT** control.
- On the system keyboard, pressing the **Superkey** and another designated key (for example, **2D Maps**) allows you to quickly change a system parameter without using the menu on which the parameter appears.


- Pressing a key or control the first time initiates a mode change, function, or operation, or changes the value of a system parameter. Pressing the same key or control a second time resumes a previous mode or system parameter, cycles to the next setting, or ends the function or operation. All **MENU** controls work this way, and it can be quicker to press the **MENU** control than to select **Close**, especially to exit a submenu.
- On a menu, protocol, or other display, text that is lighter in color than the other text on the display indicates that the item or name contained within the boundaries is not available for selection in that menu, protocol, or display.
- A  or  indicates an option or alternative for selection.
- A  or  indicates that an option or alternative has been selected.
- Selecting **Close** from a menu or display removes the menu or display from the screen.
- Selecting + or **–** increases or decreases the value of the parameter.
- An ellipsis ... on a menu indicates that a submenu is available from the selection.
- To highlight a menu, protocol, or other display item, use the trackball to move the cursor to the particular item.
- To enter text into a text field, use the keyboard.
- The softkeys, located on the lower right of the control panel, assume functions based on your control selections. For example, pressing **VCR CTRL** results in the softkeys assuming these VCR control functions: **PLAY**, **PAUSE**, **STOP**, **FF** (Fast Forward), and **REWIND**.

System Upgrades and Manual Set Updates

ATL Ultrasound is committed to innovation and continued improvement. Upgrades may be announced that consist of hardware or software improvements. Updated manuals will accompany those system upgrades.

Customer Comments

If you have questions about the manual set, or you discover an error in the manual set, please call the ATL Customer Service at **(800) 433-3246**; or if you are outside the USA, call the nearest ATL office, listed later in this section. You can also send electronic mail (e-mail) to ATL Technical Publications at the following address:

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Scanheads

The scanhead that you select is the most important factor in image quality. Optimal imaging cannot be attained without the correct scanhead. The system is optimized for use based on your scanhead selection.

Scanhead Surface Temperature Limit

The system limits patient contact temperature to 41 degrees Celsius, and acoustic output values to their respective U.S. Food and Drug Administration limits. A power monitor protection circuit protects against over-current conditions. If the power monitor protection circuit senses an over-current condition, then the drive current to the scanhead is shut off immediately, preventing overheating of the scanhead surface and limiting acoustic output. Validation of the power monitor protection circuit is performed under normal system operation.

Scanhead Selection

Pressing the **Scanhead** key displays the **Scanhead** display (Figure 2-1). From this display, you select a scanhead, a clinical option (listed in the left column on the **Scanhead** display), and a Tissue Specific preset (listed in the right column on the **Scanhead** display). Having selected these, the system runs through a set routine: it calibrates the scanhead; enables the scanhead for operation; and updates system status to reflect scanhead type, the clinical option, and the Tissue Specific preset you selected. On the **Scanhead** display, the scanheads are represented by symbols (Figure 2-2). Table 2-1 provides scanhead selection information.

Clinical Options and Applications

The system is used for diagnostic ultrasound imaging or fluid-flow analysis of the human body in the following applications: fetal, abdominal, ophthalmic, intraoperative, pediatric, small organ, neonatal and adult cephalic, pediatric and adult cardiac, transesophageal, transrectal, transvaginal, peripheral vessel, and laparoscopic.

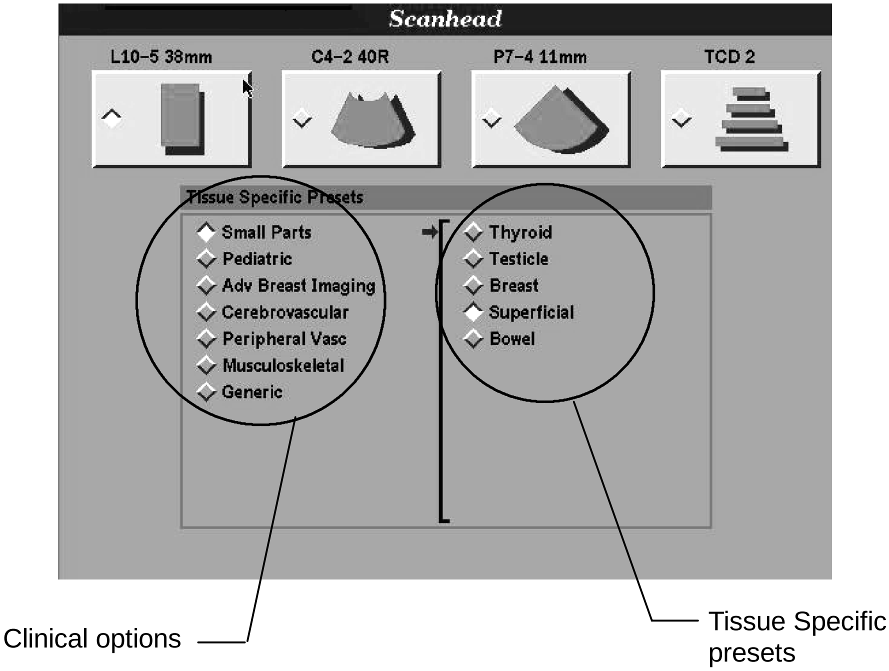


Figure 2-1. Scanhead Display

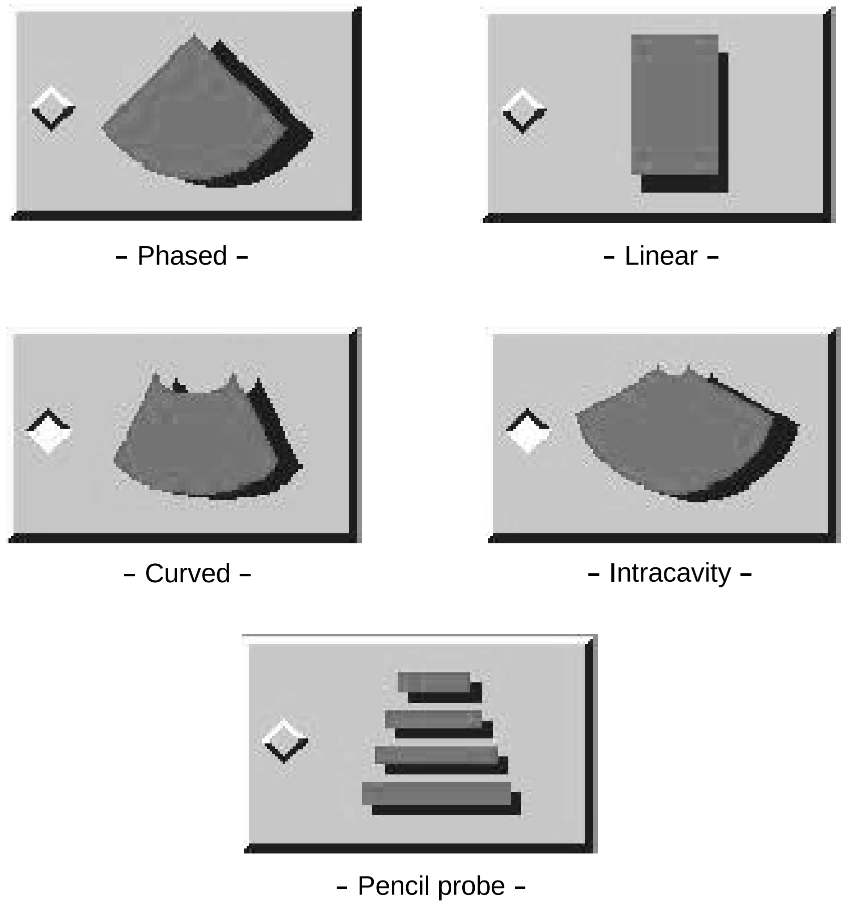


Figure 2–2. Scanhead Symbols

Table 2-1. Scanhead Clinical Options

Scanhead	Clinical Options
C4–2	Abdomen, Generic, Gyn/Fertility, OB
C5–2	Abdomen, General Imaging (CSI), Gyn/Fertility, OB
C7–4	Abdomen, Generic, Gyn/Fertility, OB, Pediatric
C8–4v	Generic, Gyn/Fertility, OB
C8–5	Cerebrovascular, Generic, Musculoskeletal, Neurosurgery, OB, Pediatric, Pediatric Cardiology, Peripheral Vascular, Small Parts
C9–5 ICT	Generic, Gyn/Fertility, OB, Prostate
CL10–5	Adult Cardiology, Cerebrovascular, Generic, Musculoskeletal, Neurosurgery, Pediatric, Peripheral Vascular, Small Parts, Vascular Surgery
CT8–4	Abdominal Surgery, Generic
L7–4	Advanced Breast Imaging, Cerebrovascular, Generic, Musculoskeletal, Pediatric, Peripheral Vascular, Small Parts
L10–5	Advanced Breast Imaging, Cerebrovascular, Generic, Musculoskeletal, Pediatric, Peripheral Vascular, Small Parts
L12–5 38mm	Advanced Breast Imaging, Cerebrovascular, General Imaging Contrast, Generic, Musculoskeletal, Pediatric, Peripheral Vascular, Small Parts
L12–5 50mm	Advanced Breast Imaging, Cerebrovascular, General Imaging Contrast, Generic, Musculoskeletal, Pediatric, Peripheral Vascular, Small Parts
LAP L9–5	Abdominal Surgery, Generic
LI9–5 33mm	Abdominal Surgery, Generic

Table 2-1. Scanhead Clinical Options (Continued)

Scanhead	Clinical Options
P3-2	Abdomen; Adult, Pediatric, and CSI Cardiology; Gyn/Fertility; Generic; OB; Transcranial Doppler
P4-2	Abdomen; Adult, Pediatric, and CSI Cardiology; Gyn/Fertility; Generic; OB; Transcranial Doppler
P5-3	Abdomen; Adult, Pediatric, and CSI Cardiology; Generic; Gyn/Fertility; OB; Pediatric
P6-3	Abdomen, Generic, Gyn/Fertility, OB, Pediatric
P7-4	Adult and Pediatric Cardiology, Cerebrovascular, Generic, Neurosurgery, OB, Pediatric
BPT9-5	Pediatric Transesophageal Cardiology, Generic
MPT7-4	Adult Transesophageal Cardiology, Generic
D2 TC	Transcranial Doppler, Generic
CW 2	Adult and Pediatric Cardiology, Generic
CW 5	Cerebrovascular, Generic, Peripheral Vascular
CW 10	Generic, Peripheral Vascular

Doppler Maximum Measurable Velocity (MMV)

The accuracy with which MMV can be measured is related to the accuracy of the parameters shown in Table 2–2. The Doppler maximum measurable velocities with an accuracy of ±1% are shown in Table 2–3 and Table 2–4. If angle correction is used, the MMV will increase. For example, with an angle correction of 60°, the MMV will be twice that listed in Table 2–3. See Figure 2–3 for the variation of accuracy with Doppler angle.

Table 2–2. Doppler Accuracy

Parameter	Systematic Error	Notes
Doppler frequency	¦ 0.4 %	As a function of maximum frequency
Doppler angle	¦ 1°	See Table 2–3 and Figure 2–3
Velocity	¦ 0.4 %	As a function of maximum velocity at 0° Doppler angle
Time	¦ 2.5 ms ¦ 5 ms ¦ 10 ms	Slow scroll rate Medium scroll rate Fast scroll rate

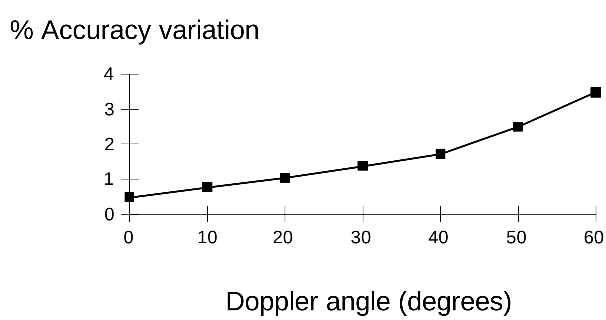


Figure 2–3. Accuracy Variation with Doppler Angle

Table 2-3. Doppler Maximum Measurable Velocities: Pulsed Wave

Scanhead	Doppler Frequency (MHz)	Angle Correction (degrees)	MMV (meters/sec)
C4–2	2.5	0	7.0
C5–2	2.5	0	7.0
C7–4	4.0	0	4.4
C8–4v IVT	6.0	0	3.5
C8–5	6.0	0	3.5
C9–5 ICT	6.0	0	3.5
CT8–4	4.0	0	4.4
D2 TC	2.0	0	8.8
L7–4	4.0	0	4.4
L10–5	6.0	0	2.9
CL10–5	6.0	0	2.9
L12–5 38 mm	6.0	0	2.9
L12–5 50 mm	6.0	0	2.9
LAP L9–5	6.0	0	2.9
LI9–5	6.0	0	2.9
BPT9–5	6.0	0	2.9
MPT7–4	4.0	0	4.4
P3–2	2.0	0	8.8
P4–2	2.0	0	8.8
P5–3	3.0	0	5.8
P6–3	3.0	0	5.8
P7–4	4.0	0	4.4

Table 2–4. Doppler Maximum Measurable Velocities: Continuous Wave

Scanhead	Doppler Frequency (MHz)	Angle Correction (degrees)	MMV (meters/sec)
D2 CW	2.0	0	19.3
D5 CW	5.0	0	7.7
D10 CW	10.0	0	3.9
BPT9–5	5.0	0	7.7
MPT7–4	4.0	0	9.6
P3–2	2.0	0	19.3
P4–2	2.0	0	19.3
P5–3	3.0	0	12.8
P7–4	4.0	0	9.6

Scanhead Maintenance

Scanheads require proper care, cleaning, and handling. Reasonable care includes inspection, cleaning, and disinfection or sterilization, as necessary.

Inspect the scanhead cable, case, and lens before each use. Check for cracks or other damage that jeopardizes the integrity of the scanhead. Report any damage to your ATL Ultrasound Customer Service Representative, and discontinue use of the scanhead.

CAUTION

Some ultrasound coupling gels, cleaning, disinfecting, and sterilizing solutions can damage a scanhead. Before using a gel or solution on a scanhead, refer to *Using Disinfectants and Gels,* part number 4700-0249, -16 or higher.

Acoustic Artifacts

The transducer adds its own signature to the echo information in the form of beam width effects, axial resolution limitations, and frequency characteristics. The control choices made by the sonographer that affect amplification, signal processing, and echo signal display can lead to significant differences in the displayed appearance of echo data. Following is a brief discussion of acoustic artifacts. An understanding of the physical basis for the production of signals displayed on ultrasound images is helpful in minimizing artifacts on images and interpreting the results of studies.

An artifact is an echo displayed in a different position than its corresponding reflector in the body. Artifacts can also be caused by intervening tissue properties. Artifacts can originate from external noise, reverberations, multi-path reflections, or misadjusted equipment. They can also come from the ultrasonic beam geometry and unusual changes in beam intensity. Artifacts and their manifestations are listed below, and following are some definitions of various artifacts.

- Added objects displayed as speckle, section thickness, reverberation, mirror image, comet tail, ring down.
- Missing objects due to poor resolution.
- Incorrect object brightness due to shadowing or enhancement.
- Incorrect object location due to refraction, multi-path reflections, side lobes, grating lobes, speed error, or range ambiguity.
- Incorrect object size due to poor resolution, refraction, or speed error.
- Incorrect object shape due to poor resolution, refraction, or speed error.

Comet tail is a form of reverberation artifact produced when two or more strong reflectors are close together and have a high propagation speed. In this case, sound does not travel directly to a reflector and back to the transducer; and a strong linear echo appears at the reflector and extends deeper than the reflector.


Enhancement is an increased relative amplitude of echoes caused by an intervening structure of low attenuation.

Focal enhancement, also known as focal banding, is the increased intensity in the focal region that appears as a brightening of the echoes on the display display.

Mirror imaging artifact is most commonly seen around the diaphragm; this artifact results from sound reflecting off another reflector and back.

Multi-path positioning and refraction artifacts describe the situation in which the paths to and from a reflector are different. The longer the sound takes traveling to or from a reflector, the greater the axial error in reflector positioning (increased range). Refraction and multi-path positioning errors are normally relatively small and contribute to general degradation of the image rather than to gross errors in object location.

A propagation speed error occurs when the assumed value for propagation speed by the ultrasound system is incorrect. If the actual speed is greater than that assumed, the calculated distance to a reflector is too small, and the reflector will be displayed too far from the transducer. Speed error can cause a structure to be displayed with incorrect size and shape.

In ultrasound imaging, it is assumed that for each pulse produced, all reflections are received before the next pulse is sent out. If this is not the case, range ambiguity can result. The ultrasound system calculates the distance to a reflector from the echo arrival time assuming that all echoes were generated by the last emitted pulse. The maximum depth to be imaged unambiguously by the system determines its maximum pulse repetition frequency.

Reverberation is the continuing reception of a particular signal because of reverberation rather than reflection from a particular acoustic interface. This phenomenon is analogous to the effect created by mirrors positioned on opposite walls when an object, a head for instance, is placed between the mirrors. The image of the head is reflected back and forth infinitely between the two mirrors, creating the optical illusion of multiple heads. Reverberations are easily identifiable, because they are equally spaced on the display display.

A condition of acoustic saturation occurs when received signals reach a system's high-amplitude limit. At that point the system becomes unable to distinguish or display signal intensities. At the point of saturation, increased input will not increase output.

Scattering is the diffuse, low-amplitude sound waves that occur when acoustic energy reflects off tissue interfaces smaller than a wavelength. In diagnostic ultrasound, Doppler signals come primarily from acoustic energy back-scattered from red blood cells.

Shadowing is the reduction in echo amplitude from reflectors that lie behind a strongly reflecting or attenuating structure. This phenomenon occurs when scanning a lesion or structure with an attenuation rate higher than that of the surrounding tissue. The lesion causes a decrease in beam intensity, which results in decreased echo signals from the structures beyond the lesion. Consequently, a dark cloud behind the lesion image forms on the display. This cloud, or shadow, is useful as a diagnostic clue.

Side lobes (from single-element transducers) and grating lobes (from array scanheads) cause objects that are not directly in front of the transducer to be displayed incorrectly in lateral position.

Speckle appears as tissue texture close to the transducer but does not correspond to scatterers in tissue. It is produced by ultrasound wave interference and results in general image degradation.

Speed of sound artifacts occur if the sound propagation path to a reflector is partially through bone, and the speed of sound is greater than in the average soft tissue. Echo position registration artifacts will be produced. Reflectors appear closer to the transducer than their actual distance because of this greater speed of sound, resulting in a shorter echo transit time than for paths not containing bone.

When the detected Doppler frequency exceeds the Nyquist limit, aliasing occurs. It is characterized on the spectral display by the Doppler peaks going off the display, top or bottom, and then continuing on the other side of the baseline. On the Color display an immediate change in color from one Nyquist limit to the other is seen.

Mirroring is the appearance of artifacts on a spectral display when there is improper separation of forward and reverse signal processing channels. Consequently, strong signals from one channel mirror into the other.

Spectral broadening is a display phenomenon that occurs when the number of energy-bearing Fourier frequency components increases at any given point in time. As a consequence, the spectral display is broadened. Spectral broadening can indicate the disturbed flow caused by a lesion, and therefore it is important diagnostically. However, broadening can also result from interaction between flow and sample volume size, in which case it is an artifact.

Transesophageal Scanheads

The MPT7-4 and the BPT9-5 transesophageal scanheads are both available for use with the system. The MPT7-4 is a multi-plane transesophageal scanhead for adult cardiology applications, and the BPT9-5 is a bi-plane transesophageal scanhead for pediatric cardiology applications. The transesophageal scanheads can be used for 2D and M-mode imaging, pulsed-wave and continuous-wave Doppler, Color flow, and Power imaging.

Transesophageal scanhead applications include monitoring of cardiac ventricular function by anesthesiologists of patients during cardiac and long non-cardiac surgery; pre- and post-operative evaluation of cardiac valvular surgery; and general diagnostic and outpatient imaging of difficult-to-image patients. Potential future applications include coronary artery examination and evaluation.

Transesophageal echocardiography in pediatric patients can be performed safely, but attention must be paid to possible airway obstruction or hemodynamic compromise. For additional information see the following references:

- Gilbert, T.B., Panico, F.G., McGill, W.A., Martin, G.R., Halley, D.G., and Sell, J.E. “Bronchial Obstruction by Transesophageal Echocardiography Probe in a Pediatric Cardiac Patient.” *Anesth Analg,* Vol. 74: 156–158, 1992.
- Muhiudeen, I., and Silverman, N. “Intraoperative Transesophageal Echocardiography Using High Resolution Imaging in Infants and Children with Congenital Heart Disease.” *ECHOCARDIOGRAPHY: A Jrnl. of CV Ultrasound & Allied Tech.,* Vol. 10, No. 6: 599–608, November 1993.
- Muhiudeen, I.A., Silverman, N.H., and Anderson, R.H. “Transesophageal Transgastric Echocardiography in Infants and Children: The Subcostal View Equivalent.” *Journal of the American Society of Echocardiography,* Vol. 8, No. 3: 231–244, May–June, 1995.
- Stevenson, J.G., “Role of intraoperative transesophageal echocardiography during repair of congenital cardiac defects.” *Acta Paediatric Suppl,* 410: 23–33, 1995.
- Stevenson, J.G., and Sorensen, G.K. “Proper Probe Size for Pediatric Transesophageal Echocardiography.” *THE AMERICAN JOURNAL OF CARDIOLOGY,* Vol. 72: 491–492, August 15, 1993.

Description

MPT7-4

The MPT7-4 consists of a multi-element ultrasound phased array mounted on an endoscope. The transducer elements are electronically time- and phase-coordinated to generate a steered and focused ultrasound beam. The scanhead is capable of imaging in multiple scan planes. At 0-degree orientation, the acquired tomographic plane is equivalent to the transverse plane, and at approximately 90-degree orientation, longitudinal plane images can be obtained with the transducer array about 30 cm from the patient's teeth. The transducer array can be rotated up to 180 degrees, which provides a mirror image of the 0-degree orientation. Multiple tomographic image planes are continuously selected by rotating the transducer array without significant manipulation of the MPT7–4. Manipulation of the transducer array is accomplished by flexion of the endoscope tip with the articulation controls.

BPT9-5

The BPT9-5 consists of two fixed phased array transducers mounted on an endoscope. The proximal transducer array is oriented inline or parallel with the endoscope, and the distal transducer array is oriented perpendicular to the endoscope. Two switches on the control module select between the two phased arrays. The distal switch selects the transverse array; the proximal switch selects the longitudinal array.

The BPT9-5 is capable of imaging in transverse or longitudinal scan planes. Off-axis image planes are obtained by changing the orientation of the endoscope tip relative to the body or heart. Manipulation of the two phased arrays by flexion of the endoscope tip is accomplished with the articulation controls.

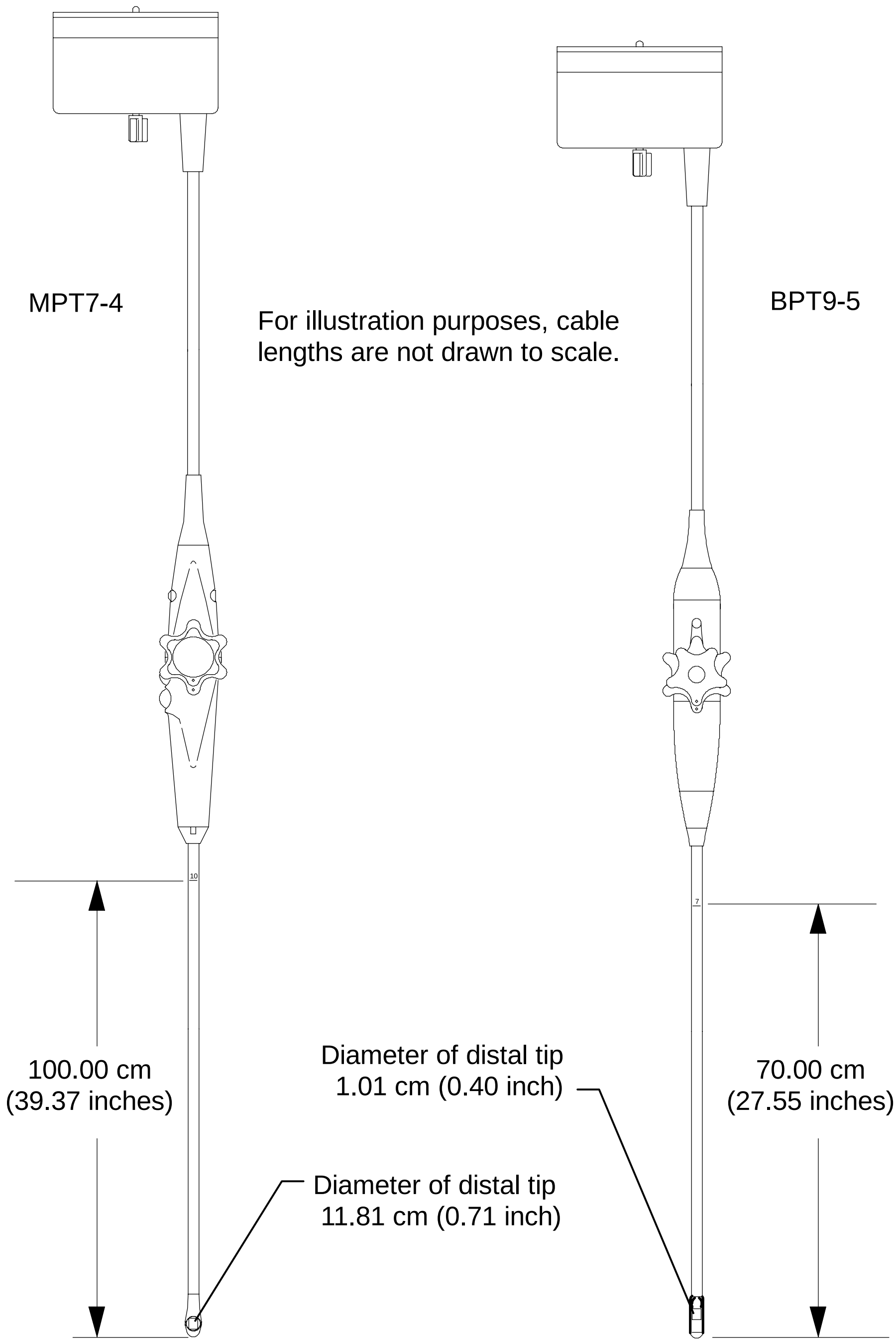


Figure 3–1. Critical Dimensions of the Transesophageal Scanheads


Scanhead Characteristics

The maximum acoustic power and intensity values for all scanheads, including the transesophageal scanheads, are listed in *Acoustic Output Tables*, 4706-0027-XX.

Refer to Table 3–1 for a list of characteristics of the transesophageal scanheads.

Table 3–1. Scanhead Characteristics

Scanhead Characteristic		MPT7-4	BPT9-5
Endoscope diameter		0.95 cm	0.83 cm
Transducer diameter		1.81 cm	1.01 cm
Endoscope length		100 cm	70 cm
Articulation ranges	Left/right	± 60_	± 60_
	Posterior	60_	60_
	Anterior	120_	120_

Articulation

Articulation is controlled by two knobs on the handle of the scanhead (Figure 3–2 and Figure 3–3). You can move the scanhead tip through articulating ranges of 60 degrees to the left through 60 degrees to the right and 60 degrees posteriorly through 120 degrees anteriorly.

For the MPT7-4, a scan plane position icon appears on the image display to the right of the image. The scan plane position icon displays the current scan plane position relative to the scanhead tip (Figure 3–4). The number to the left of the MPT7-4 scan plane position icon is the value in degrees of offset of the scan plane. For the BPT9-5, the scan plane position icon appears to the right of the image display, and the active array is indicated as shown in Figure 3–5.

The brake buttons on the MPT7-4 scanhead allow you to lock lock the articulation position. When the brake is on, a lock icon is displayed above the scan plane position icon (Figure 3–6). On the BPT9-5, the articulation mode selection lever allows continuous or detent movement of the scanhead tip (Figure 3–7). When the lock icon is displayed, the lever is in a locked position and the scanhead tip can only be moved in specific modes (Table 3–2).

Two articulation knobs are arranged one on the other. The smaller or upper knob controls the left/right articulation, and the larger or lower one controls the anterior/posterior articulation. The rotation of the two knobs is directly related to the articulation of the scanhead tip. A one-degree change in the knob corresponds to an approximate one-degree change in the scanhead tip in the selected direction (Figure 3–8).

WARNING

Do not manipulate a MPT7-4 transesophageal scanhead while inserted in a “locked” position. While it is physically possible, a hazard to the patient exists.

Scan Plane Orientation

The scan plane orientation of a transesophageal scanhead is shown in Figure 3–9 and Figure 3–10.

When you select the MPT7-4, the scan plane orientation is set to –5 degrees during initialization. Fully depressing the left and right scan plane rotation controls at the same time will also reset the scan plane orientation to the –5 degrees position.

Image Orientation

Image presentation is defined by the location of the orientation marker. Top and bottom image presentations for the MPT7-4 are shown in Figure 3–11. Top and bottom image presentations for the BPT9-5 are shown in Figure 3–12.

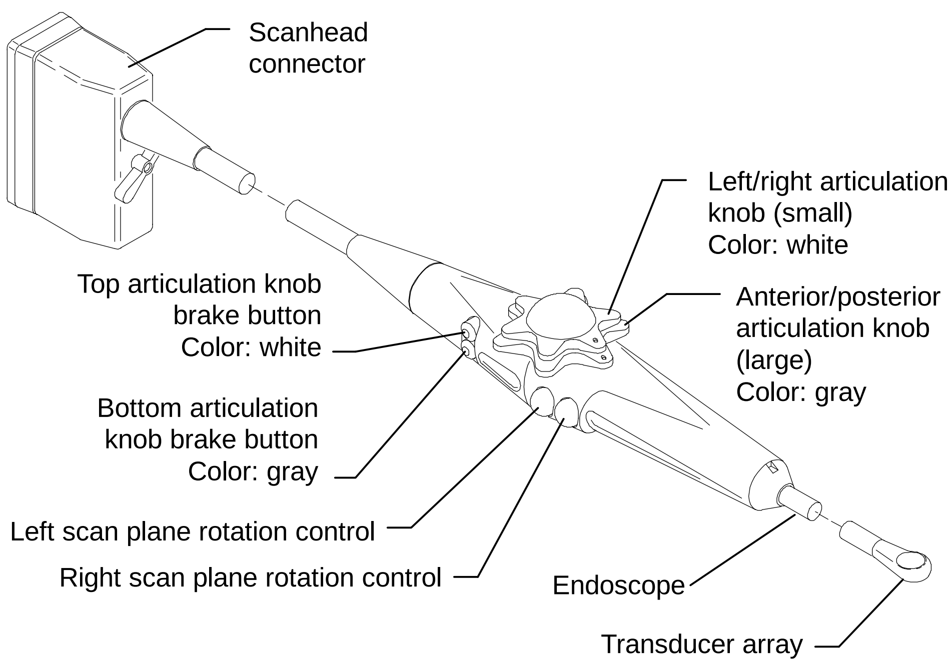


Figure 3–2. MPT7-4 Features and Control Locations

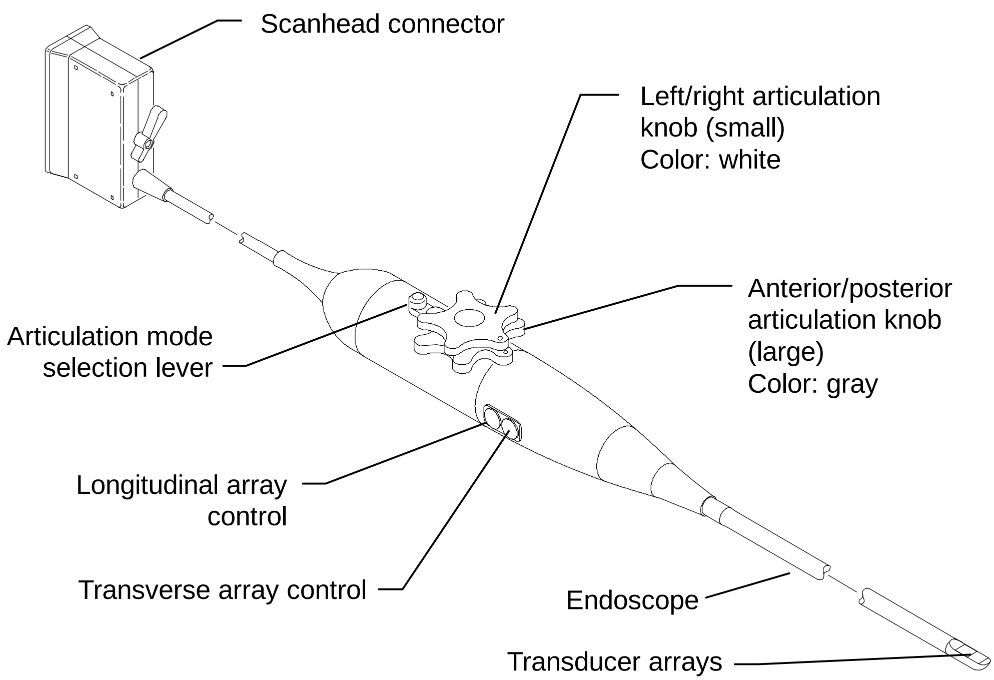


Figure 3–3. BPT9-5 Features and Control Locations

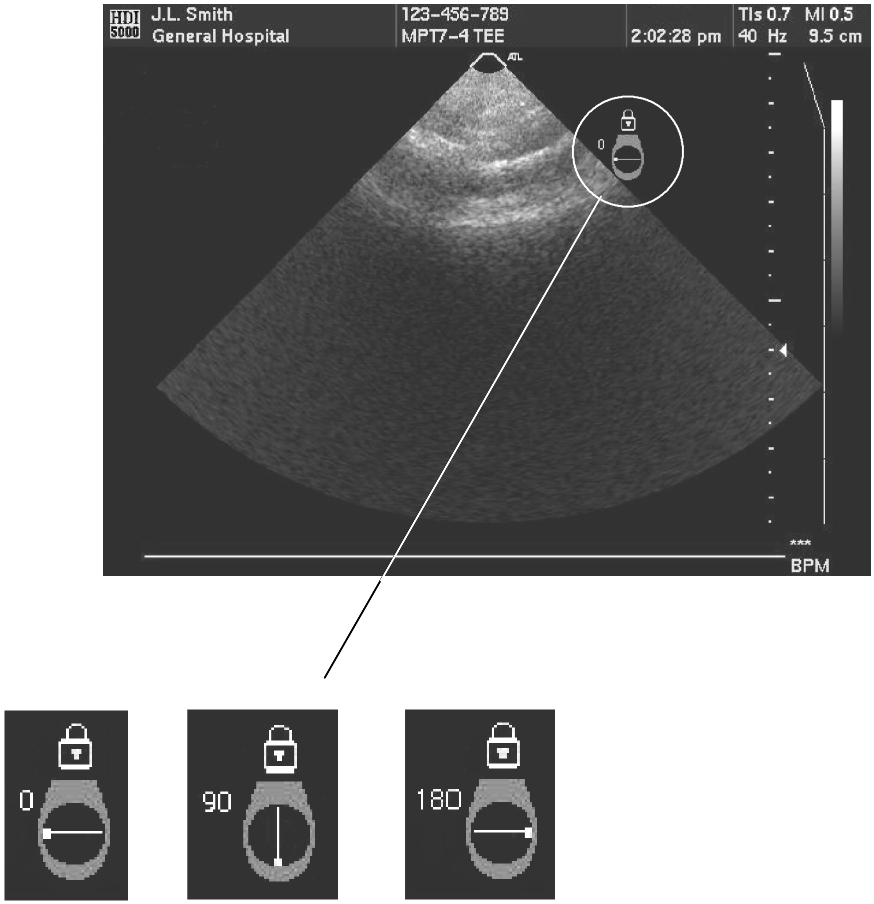
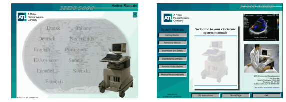


Figure 3-4. MPT7-4 Scan Plane Position Icon



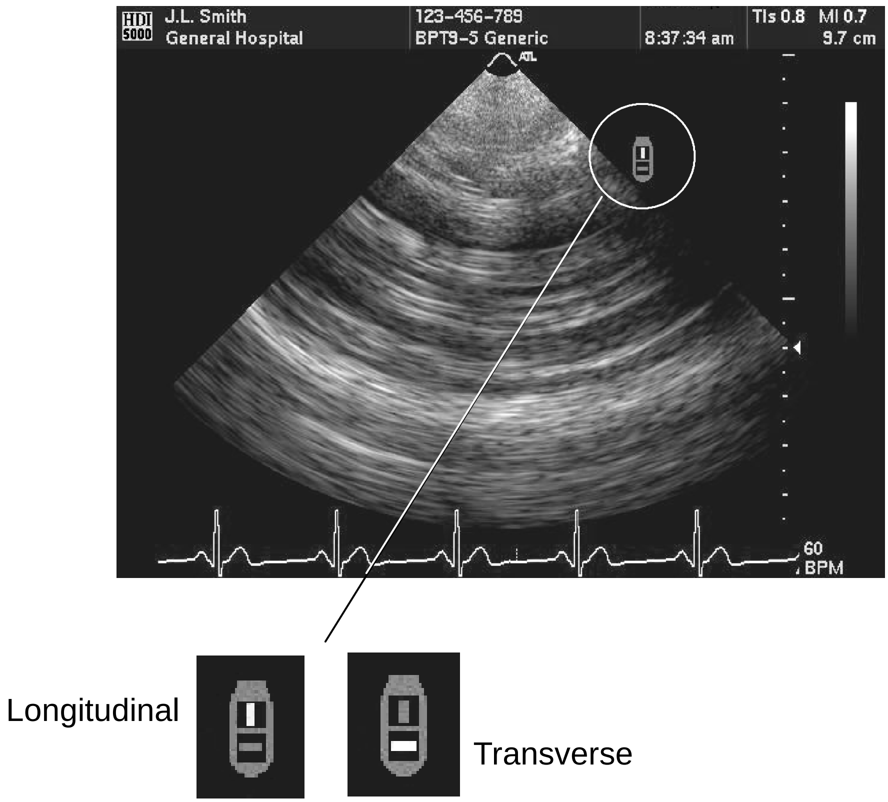


Figure 3–5. BPT9–5 Scan Plane Position Icon

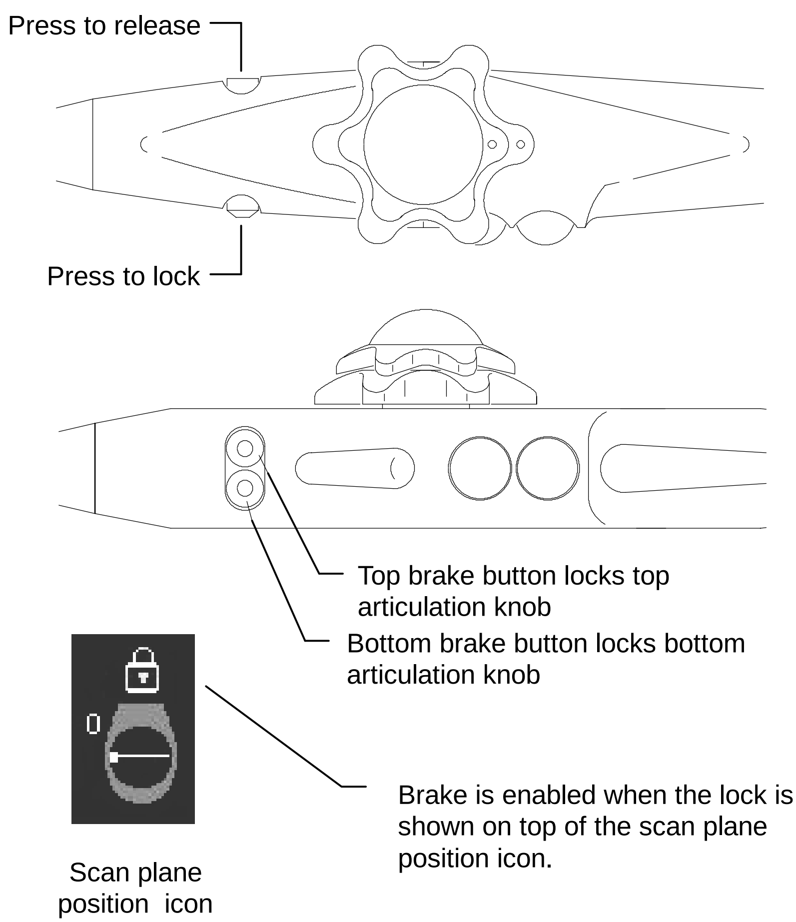


Figure 3-6. MPT7-4 Scan Plane Position Brake

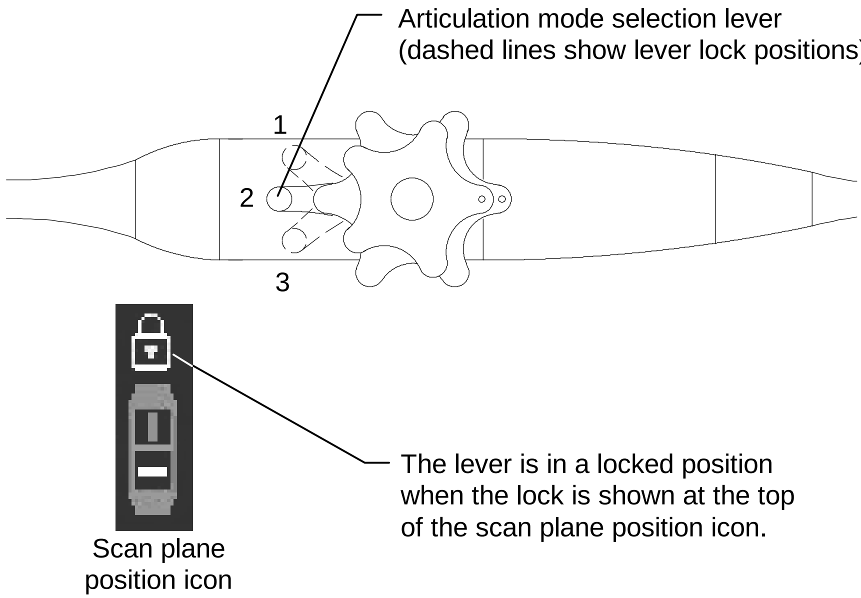


Figure 3–7. BPT9–5 Articulation Mode Selection Lever

Table 3–2. BPT9-5 Articulation Mode Selection

Lever Positions (see Figure 3–7)	Anterior/Posterior Articulation (lower knob)	Left/Right Articulation (upper knob)
1 Locked	Continuous	Detent
2 Unlocked	Continuous	Continuous
3 Locked	Detent	Detent

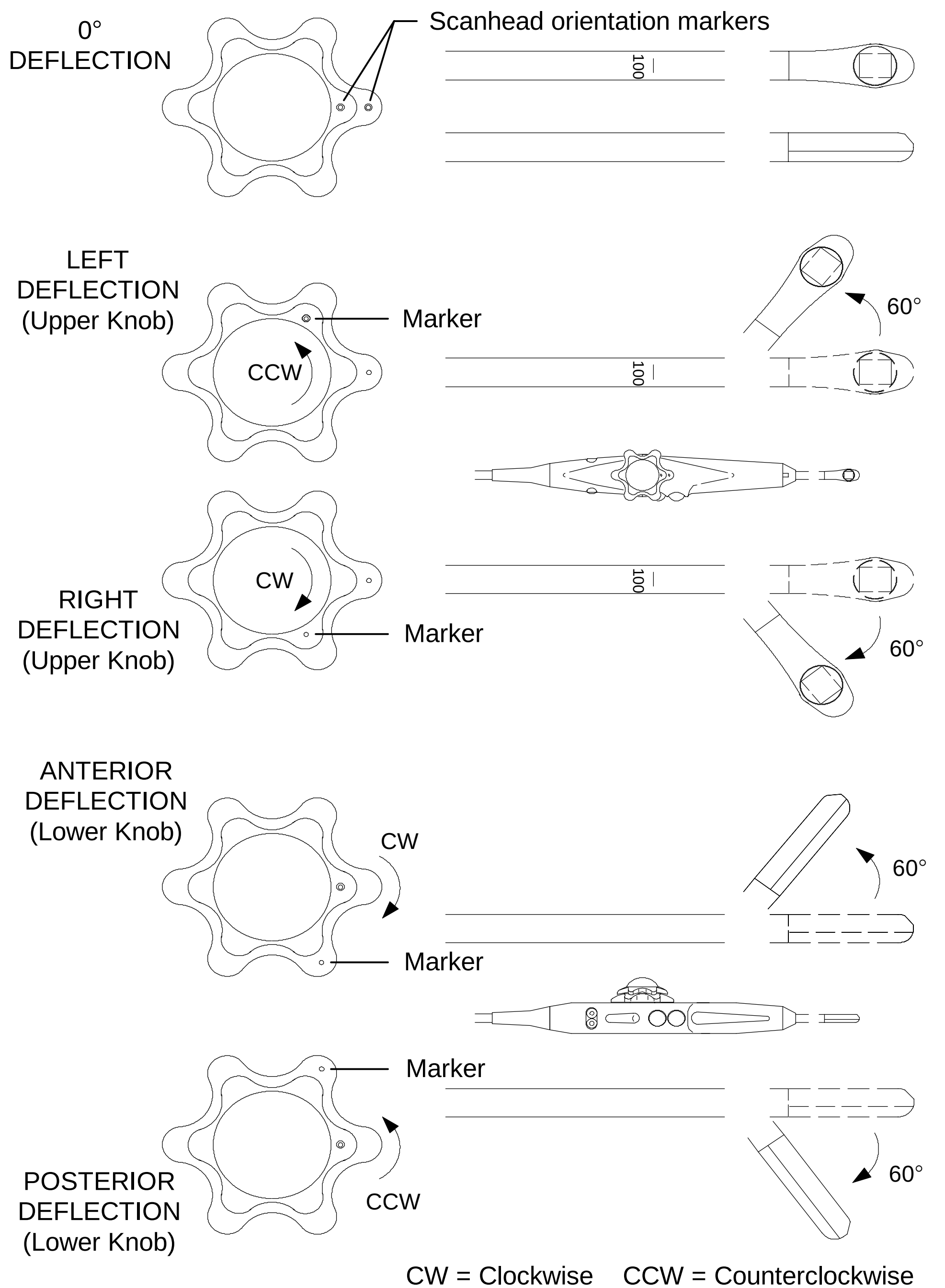


Figure 3-8. Articulating Device Deflection

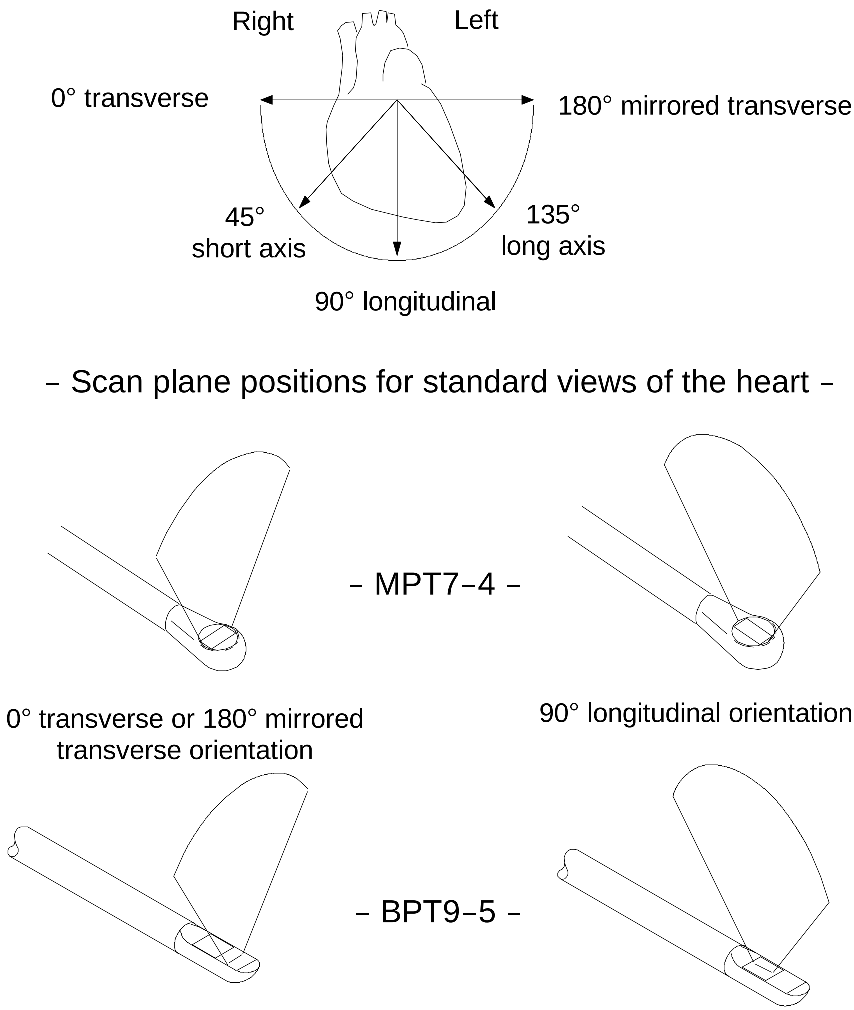
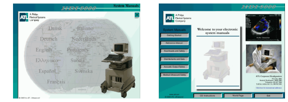


Figure 3–9. Scan Plane Orientation



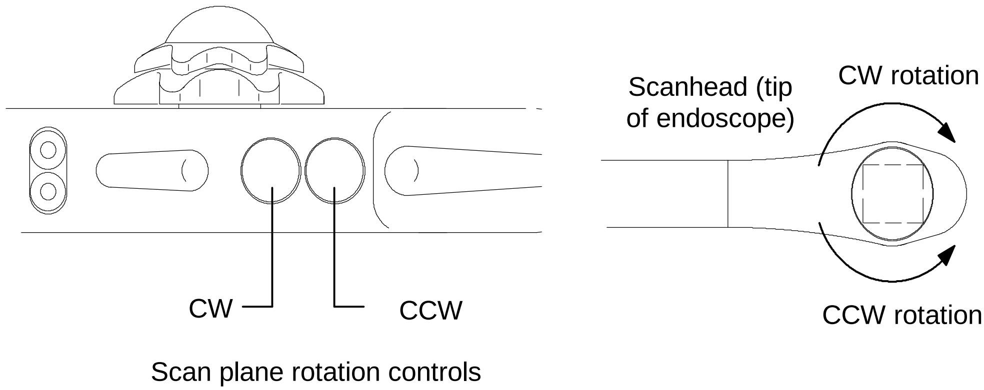


Figure 3-10. MPT7-4 Scan Plane Orientation

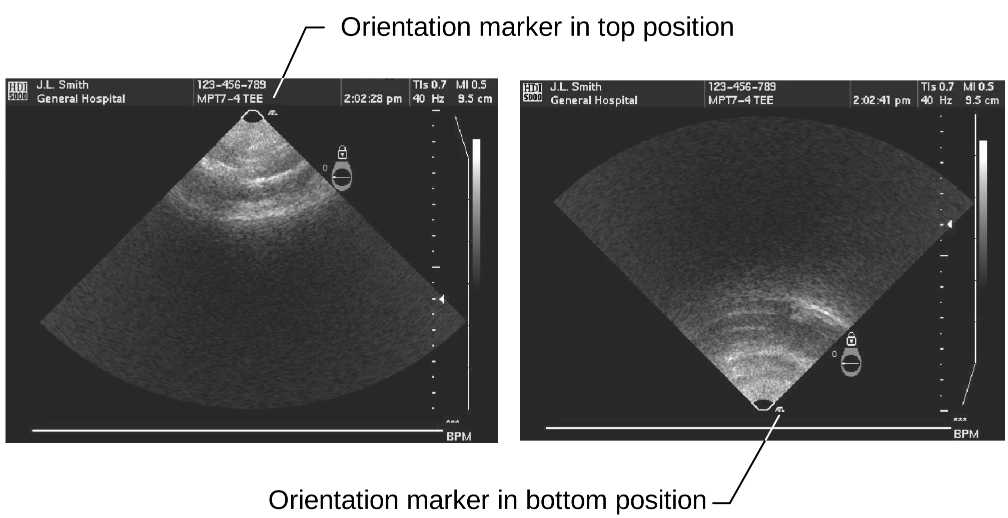


Figure 3-11. MPT 7-4 Top/Bottom Image Presentation

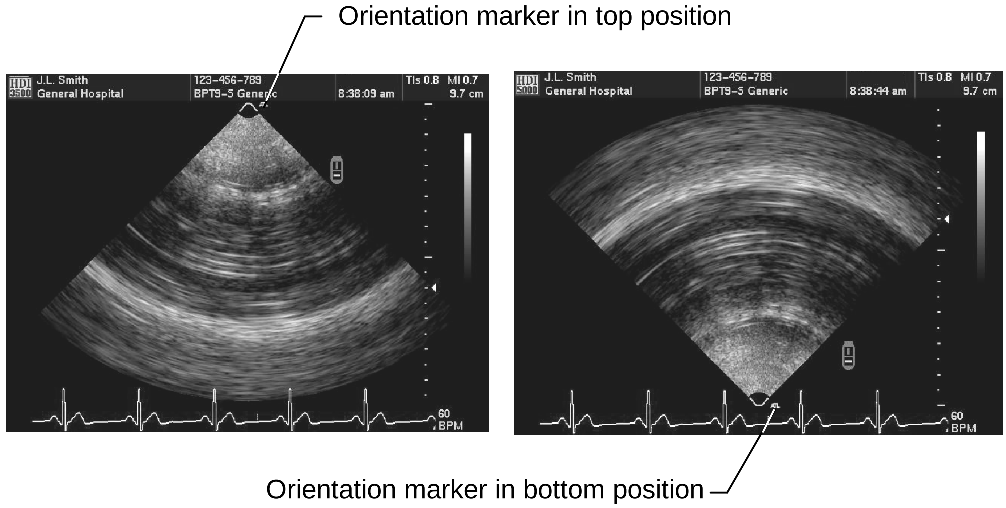


Figure 3-12. Top/Bottom Image Presentation for the BPT9-5

Thermal Monitor

As a safety precaution, a thermal sensor is mounted on the scanhead tip adjacent to the transducer array. This sensor is part of the system thermal monitoring system, which provides continual thermal monitoring at the scanhead tip while the scanhead is selected.

Bioeffects have been documented at temperatures exceeding 41 degrees Celsius. When the patient applied part temperature (PAPT) is greater than or equal to 41 degrees Celsius, the temperature will be displayed on the video monitor.

A warning is also displayed on the video monitor when the PAPT is 44 degrees Celsius:

Approaching thermal limit: currently 44 degrees C.

If this message appears, then reduce output power, lower PRF, or change imaging parameters to reduce scanhead tip heating. The temperature will be updated as it changes.

The system will assume a circuit failure at a PAPT that is greater than or equal to 45 degrees Celsius. This situation will result in an electronic disconnection of the transesophageal scanhead and the display of the following dialog on the video monitor:

Critical scanhead temperature.

Please reselect the scanhead.

Selecting **OK** on the dialog will display the **Scanhead** display. You can reselect the transesophageal scanhead from this display.

If you wish to resume scanning, use a lower power setting. If the scanhead does not enable within two minutes, or becomes disabled again, discontinue use and call an ATL Customer Service rupport Representative for service.

In extreme cases, a patient with a high fever may cause the system to disable the scanhead prematurely. If this occurs, attempt scanning at a lower output setting or change imaging modes.

Operating Instructions

Inspection

Before using the scanhead, examine it for damage to the probe tip, casing, cable, and connector.

WARNING

Do not use the scanhead if there are any signs of damage to the cable, connectors, casing, probe tip, or any other part. Notify ATL Customer SupportCustomer Service or your local ATL representative in the event of observed or suspected damage.

Scanning the Patient

WARNINGS

- A transesophageal scanhead is to be used only by a skilled, trained physician. Before scanning, the physician should be thoroughly familiar with the articulating device (scan plane orientation, range of deflection, and position indicators).
- Prior to each exam, examine the scanhead for damage.
- Most scanheads cannot be sterilized. When sterility is required, use a sterile probe cover and gel. Refer to *Using Disinfectants and Gels*, 4700-0249, -16 or higher
- Do not manipulate a transesophageal scanhead while inserted in a “locked” position (refer to “Articulation”). While it is physically possible to do so, it is difficult for the operator to gauge the amount of pressure applied to internal surfaces, and a hazard to the patient exists.
- If you encounter resistance while manipulating the scanhead in the esophagus or stomach, stop the procedure immediately.
- Follow approved medical practices when anesthetizing and positioning the patient, inserting the scanhead into the esophagus, and locating anatomic structures. Ensure the patient’s airway remains open at all times.

CAUTION

Do not use a transesophageal scanhead without a bite guard. The scanhead can be damaged if a bite guard is not used. Mechanical damage can be very costly to repair and is not covered by the warranty. Obtain bite guards through ATL Supplies and Accessories or your local ATL representative.

" **To scan the patient with a transesophageal scanhead:**

Images can be acquired starting at the transgastric position or at the base of the heart. To help with patient comfort, efficient examination, and observance of the ALARA principle, minimize the number of scanhead excursions back and forth from the proximal esophagus to the gastric fundus.

1. Insert the bite guard into the patient's mouth.
2. Introduce the endoscope with the array lens surface of the scanhead facing toward the patient's tongue. As the scanhead enters the esophagus, a 60-degree bend in the tip of the endoscope using the articulation knobs may aid insertion; straighten the tip once the esophagus is entered.
3. Most images are acquired from points between 25 cm and 45 cm of depth with the MPT7-4 and 10 cm to 15 cm with the BPT9-5, measured from the patient's incisor teeth. Markings on the endoscope every 10 cm (measured from the scanhead tip) are provided for reference.
4. The scanhead orientation in the esophagus can be adjusted by turning the handle about the scanhead longitudinal axis; the transducer array may be deflected laterally (right/left) and anteriorly/posteriorly by rotating the articulation knobs.

Maintenance

CAUTION

Before cleaning the scanhead or using any disinfectant, refer to *Using Disinfectants and Gels,* 4700-0249, -16 or higher, for information on cleaning and compatibility of scanhead and disinfectant.

After each examination, the transesophageal scanhead should be inspected for defects with the transducer tip in the neutral position and all flexed positions. Possible defects are metallic protrusions, perforations, abrasions, cracks, or dents in the insulation. Whenever a defect is suspected, the scanhead should not be used until necessary safety inspection and repairs have been made by qualified personnel.

Visual inspection of a transesophageal scanhead does not always guarantee the integrity of the insulation. In addition to visual inspection, a leakage current test should be performed by a qualified technician prior to every exam.

Do not store the transesophageal scanhead in its case until it has been cleaned and disinfected.

Storage

Before you store or transport a transesophageal scanhead, ensure that you install the TEE tip guard over the tip of the scanhead. The TEE tip guard is a cylindrical foam protector that fits over the distal tip of the scanhead to protect the transducer from damage (Figure 3–13).

To reorder the TEE tip guard, call ATL Supplies and Accessories or your local ATL representative.

WARNING

To protect against disease transmission, do not reuse a TEE tip guard. Once you remove the TEE tip guard, dispose of it. Install a new TEE tip guard before storing or transporting the scanhead.

For long-term storage, ATL recommends that the endoscope be kept in a straight position rather than in the flexed position in the carrying case. Commercial racks that protect the flexible shaft in the straight position in a clear plastic tube are available for long-term storage.

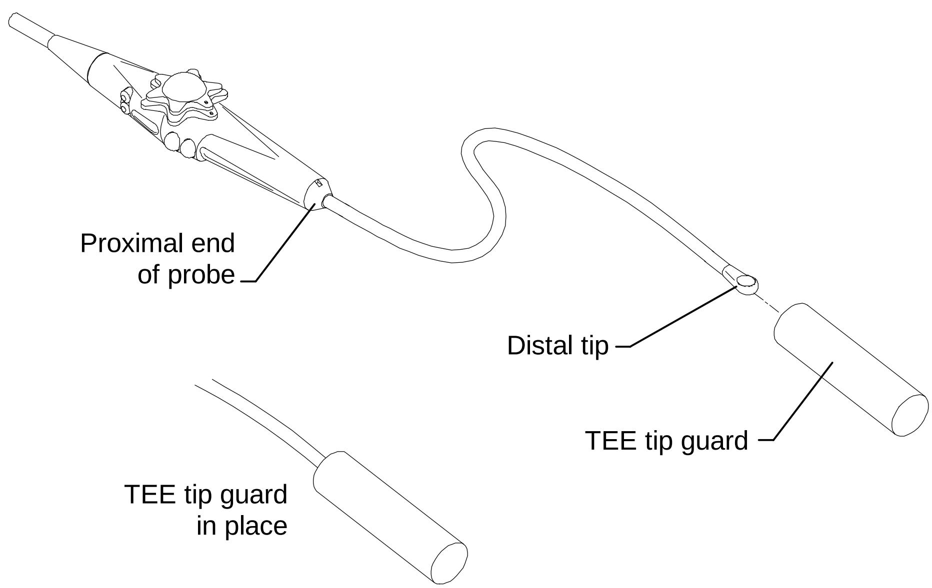
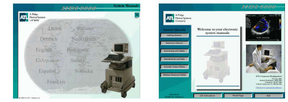


Figure 3–13. TEE Tip Guard



Laparoscopic Scanhead

The LAP L9–5 is a laparoscopic scanhead used in abdominal surgery. The scanhead can be used for 2D and M-mode imaging, pulsed-wave Doppler, Color flow, and Power imaging.

The LAP L9–5 consists of a multi-element ultrasound linear array mounted on a laparoscope. The transducer elements are electronically time- and phase-coordinated to generate a focused ultrasound beam.

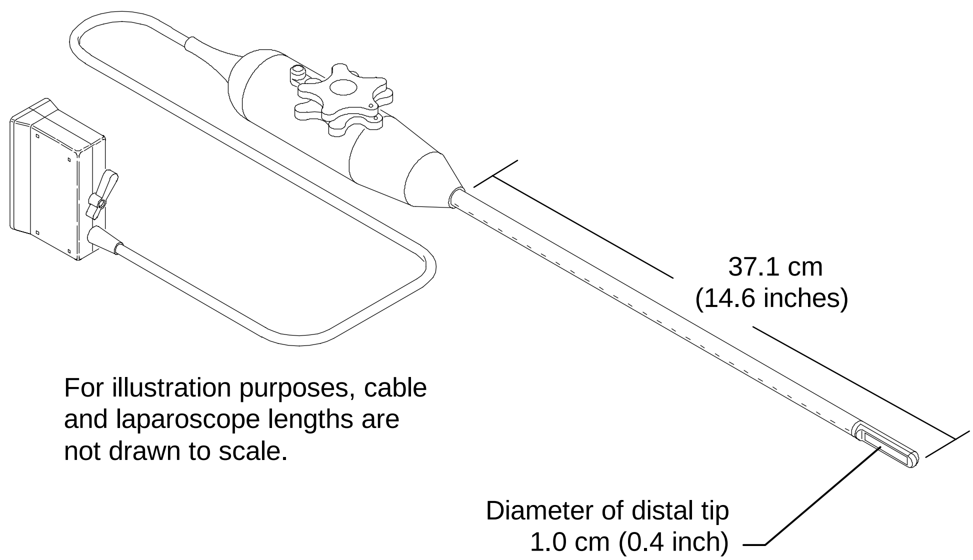


Figure 4–1. Critical Dimensions of the LAP L9–5 Scanhead

Articulation

Articulation is controlled by rotating the scanhead and by turning the two knobs on the handle of the scanhead (Figure 4–2). You can move the scanhead tip through articulating ranges of 90 degrees to the left through 90 degrees to the right and 90 degrees posteriorly through 90 degrees anteriorly. The scan plane location is marked on the laparoscope with a dotted line and is controlled by rotating the scanhead (Figure 4–2).

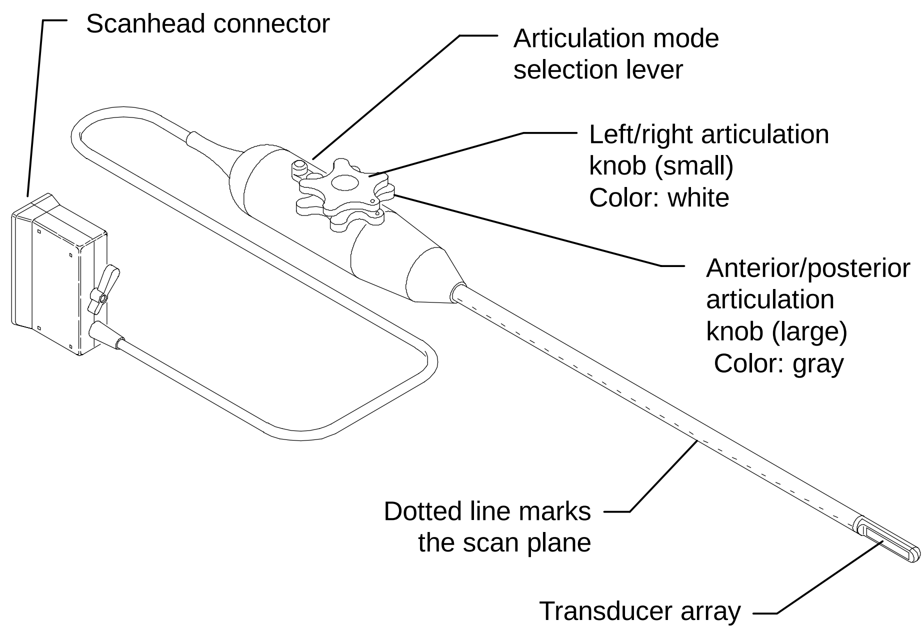


Figure 4–2. LAP L9–5 Features and Control Locations

An articulation mode selection lever on the scanhead allows you to lock the articulation position (Figure 4–3).

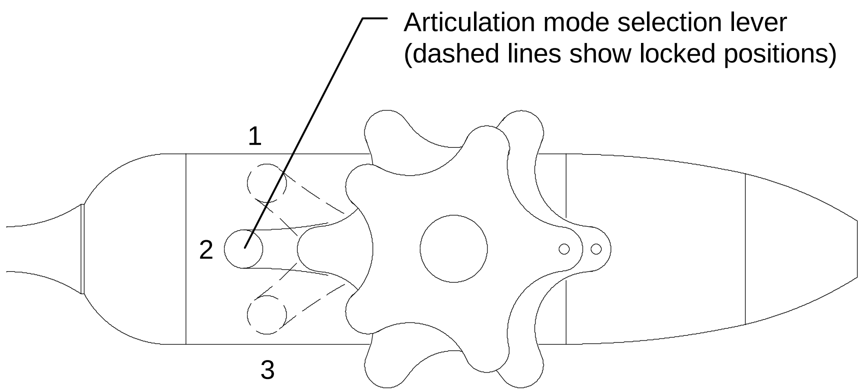


Figure 4–3. Mode Selection Lever

The two articulation knobs are arranged one on the other. The smaller or upper knob controls the left/right articulation and the larger or lower one controls the anterior/posterior articulation (Figure 4–4).

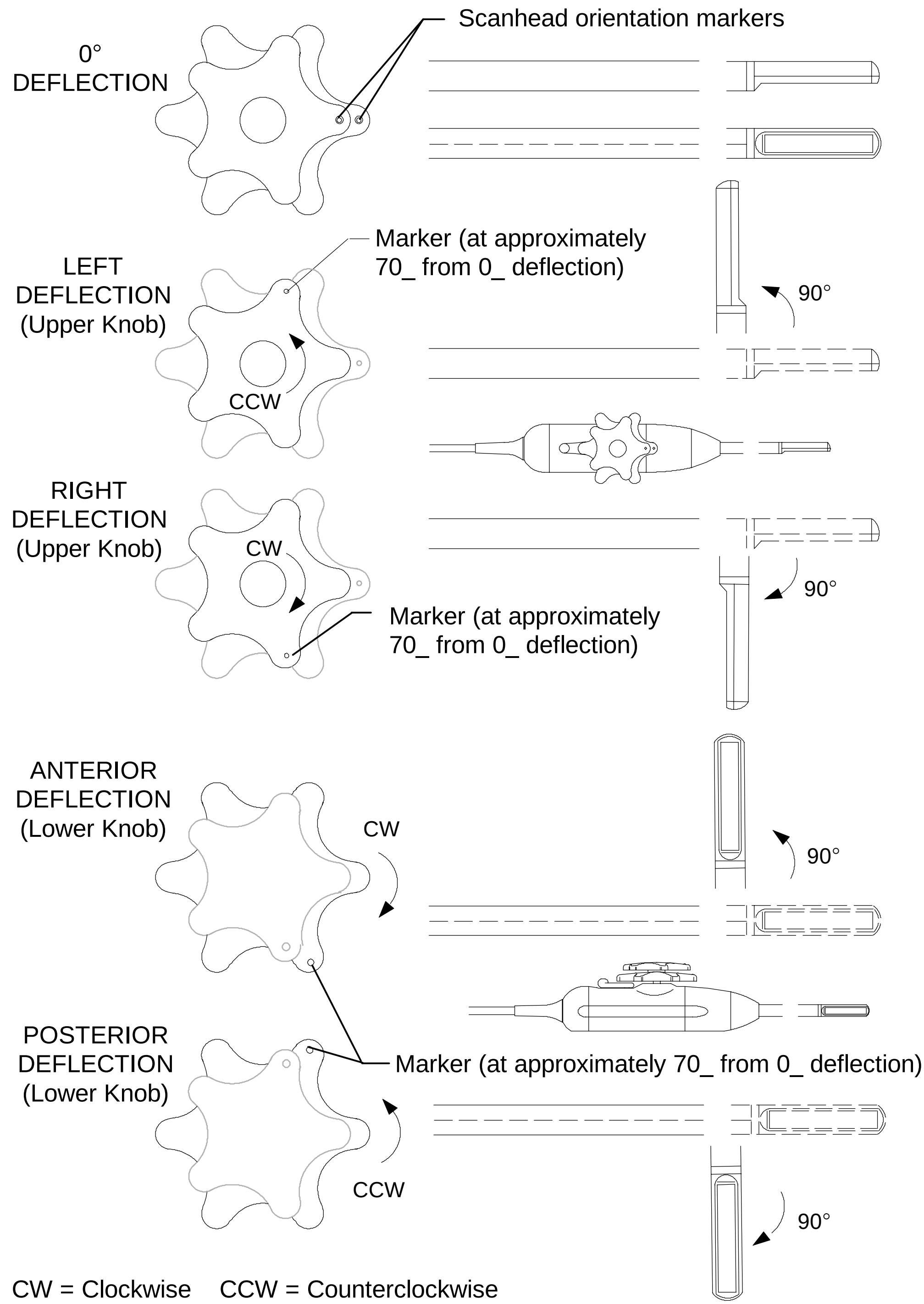


Figure 4-4. Articulating Device Deflection

LAP L9–5 Operating Instructions

Inspection

Before using the scanhead, examine it for damage to the tip, casing, cable, and connector. Inspect the patient-applied surfaces of the scanhead for sharp edges or projections.

WARNING

Do not use the scanhead if there are any signs of damage to the cable, connectors, casing, tip, or any other part. Notify ATL Customer Service or your local ATL representative in the event of observed or suspected damage.

Installing the Probe Covers

Two covers are recommended for the laproscopic scanhead: one for the laparoscope, and one for the control housing and cable. See the “Probe Covers” section.

Scanning the Patient

WARNINGS

- The scanhead is to be used only by a skilled, trained physician. Before scanning, the physician should be thoroughly familiar with the articulating devices and range of deflection.
- Prior to each exam, examine the scanhead for damage.
- When sterility is required, use a sterile probe cover and sterile gel. Refer to *Using Disinfectants and Gels,* 4700-0249, -16 or higher.
- Do not manipulate a laparoscopic scanhead while inserted in a “locked” position. While it is physically possible to do so, it is difficult for the operator to gauge the amount of pressure applied to internal surfaces, and a hazard to the patient exists.
- If you encounter resistance while manipulating the scanhead, stop the procedure immediately.
- Follow approved medical practices when anesthetizing and positioning the patient, inserting the scanhead into the abdomen, and locating anatomic structures.
- To reduce the risk of damaging the scanhead, exercise caution when using the scanhead near sharp surgical instruments.

" **To scan the patient with the LAP L9-5 scanhead:**

1. Install the sterile probe cover on the scanhead, see the “Probe Covers” section.
2. Install a 10-mm trocar into the patient’s abdomen.
3. Ensure the scanhead tip is straight.
4. Insert the scanhead through the trocar and into the abdomen.
5. The transducer array may be deflected laterally (right/left) and anteriorly/posteriorly by rotating the articulation knobs.
6. Ensure the scanhead tip is straight before removal through the trocar.

LAP L9–5 Maintenance

CAUTION

Before cleaning the scanhead or using any sterilant, refer to *Using Disinfectants and Gels*, 4700-0249, -16 or higher, for information on cleaning and compatibility of scanhead and sterilant.

After each examination, the scanhead should be inspected for defects with the transducer tip in the neutral position and all flexed positions. Possible defects are metallic protrusions, perforations, abrasions, cracks, or dents in the insulation. Whenever a defect is suspected, the scanhead should not be used until necessary safety inspection and repairs have been made by qualified personnel.

Storage

Do not store the scanhead in its case until it has been cleaned and sterilized.

For long-term storage, ATL recommends that the laparoscope be kept in a straight position rather than in the flexed position in the carrying case.


Biopsy Guides

Biopsy guides assist in the guidance of a biopsy tool. The system generates a guideline that represents the anticipated path of the biopsy tool. The echoes of the anatomical target and the tool are displayed on the video display and assist in guiding the biopsy tool to the target.

Detailed information about installation and removal of biopsy guides is shipped with the biopsy guide or bracket. For information about probe covers, refer to the "Probe Covers" section of this manual.

WARNINGS

- Inspect all components. Ensure that the biopsy guide you are using is the correct one for the scanhead, the system, and system software. Your Customer Service representative can verify this information for you.
- Alignment verification must be performed at the selected depth for the intended procedure, prior to a biopsy procedure. See "Verifying the Biopsy Guide Alignment" later in this section.
- Use only ATL-approved biopsy guides, brackets, supplies, components, and accessories. Other brands may not properly fit ATL scanheads. Improper installation may result in patient discomfort.
- The biopsy guide must be installed over a sterile probe cover. See the "Probe Covers" section of this manual.
- Most scanheads can only be disinfected; they cannot be sterilized. Only the probe cover provides the sterile barrier.
- Biopsy guides should be high-level disinfected or sterilized after each use. Refer to *Using Disinfectants and Gels,* 4700-0249, -16 or higher.

Using the Biopsy Guideline Display

To select the biopsy guideline display for the C9-5 scanhead:

1. Select the C9-5 scanhead.
2. Press the **2D/MM MENU** control to display the **2D/MMode** menu.
3. Select **Biop Sel** to display a **Biopsy Select** display (Figure 5–1).
4. Select the icon for the biopsy guide that you are using.

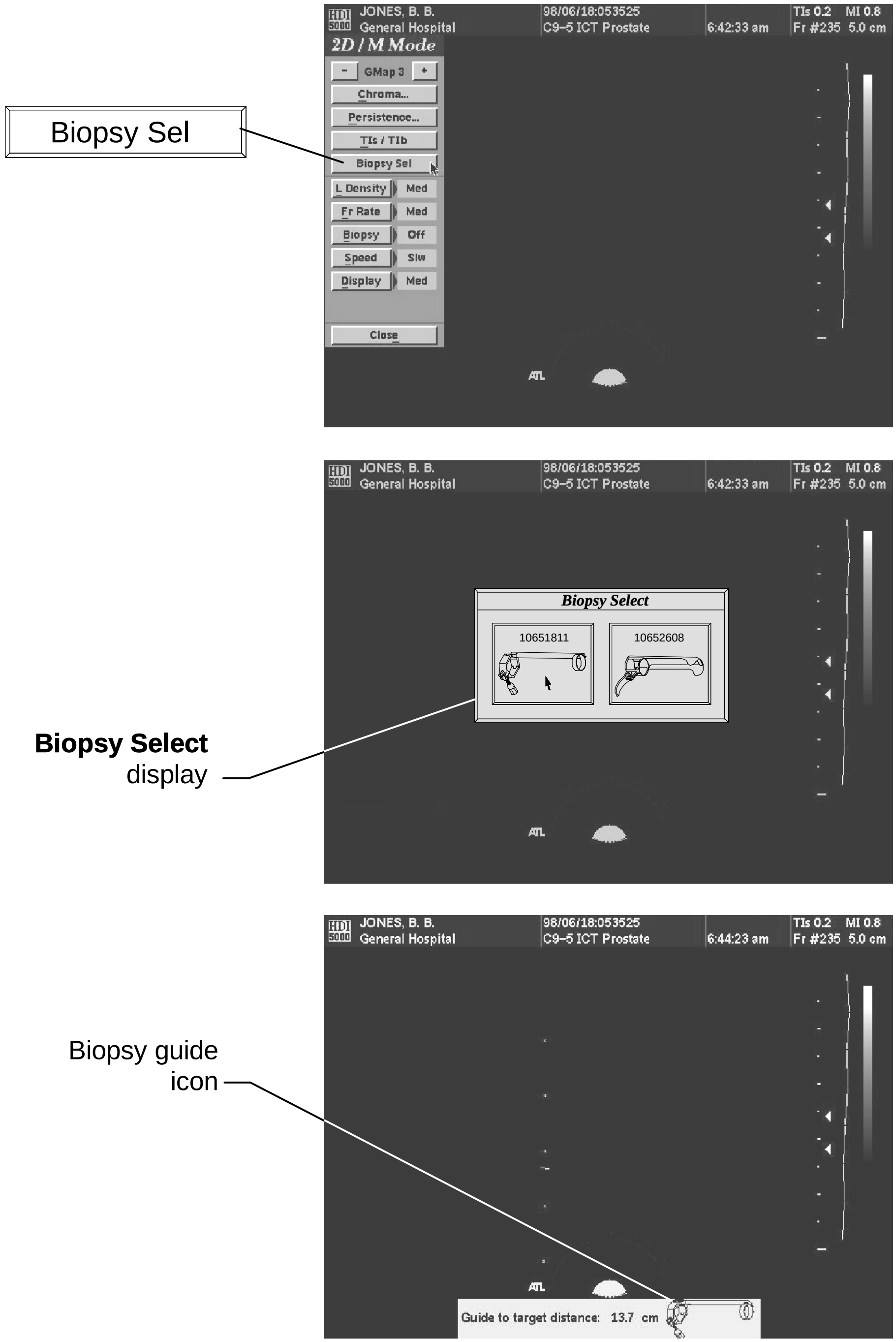


Figure 5-1. Selecting the Biopsy Guideline Display for the C9-5 Scanhead

" **To turn on the biopsy guideline:**

WARNING

In zoom, the entire biopsy guideline may not be displayed. Use the **SELECT** control and the trackball to adjust the location of the biopsy guideline and the depth cursor as necessary.

On the **2D/MMode** menu, select **Biopsy On**. (The **Biopsy Superkey** can also be used to display the biopsy guideline.)

The biopsy guideline appears on the left side of the 2D image. The exact location of the guideline is a function of the system depth setting and the scanhead. The depth cursor appears along the path of the guideline, and the **Guide to target distance measurement** value is displayed beneath the 2D image (Figure 5-2).

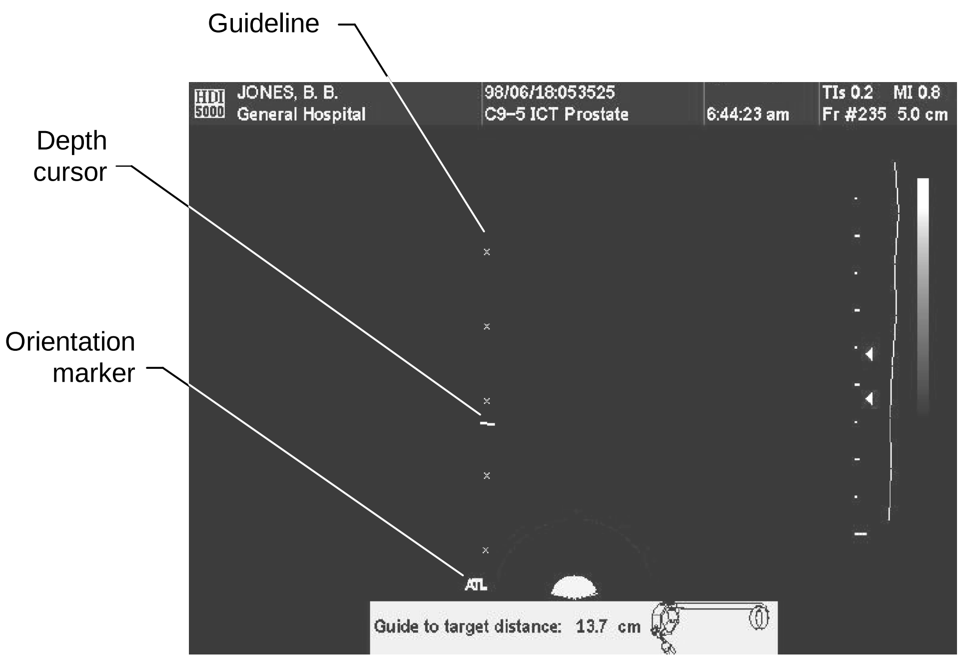


Figure 5-2. Biopsy Guideline Display (Bottom/Left Orientation)

" **To move the biopsy depth cursor:**

Rotate the trackball to move the depth cursor along the guideline.

The **Guide to target distance** measurement value changes to reflect the distance between the biopsy guide reference point origin and the depth cursor.

" **To turn off the biopsy guideline:**

On the **2D/MMode** menu, select **Biopsy Off**. (The **Biopsy Superkey** may also be used to turn off the biopsy guideline.)

The biopsy guideline, the depth cursor, and the **Guide to target distance** measurement annotation are removed from the 2D display.

Verifying the Biopsy Guide Alignment

WARNINGS

- Alignment verification is necessary prior to performing procedures with the biopsy guide.
- Do not use the biopsy guide if the needle is not following the intended path.
- The needle used for this alignment verification must not be used for the actual procedure. Always use a new, sterile needle for each biopsy procedure.
- To assist in an accurate projection of the needle, use a straight, new needle for each alignment procedure.

Perform the alignment verification before the biopsy procedure. The alignment verifies the system, scanhead, and biopsy guide relationships.

Note *The biopsy guide alignment verification is not performed for the L12-5 50 mm scanhead, instead refer to "Needle/Scan Plane Verification for the L12-5 50 mm."*

The following items are needed for the alignment verification:

- Scanhead.
- Biopsy guide or bracket (The bracket is not disposable. The type of bracket you use depends upon the scanhead you are using. For the current part number, refer to the ATL Supplies and Accessories catalog.)
- Refer to the ATL Supplies and Accessories catalog for the guide clip that fits your scanhead adapter.
- Sterile biopsy guide kit (disposable).
- New, straight, biopsy needle.
- Beaker of water (or water bath).

" **To perform an alignment verification:**

1. Attach the bracket and procedure kit or the biopsy guide to the scanhead.
2. Connect the scanhead to the system, and select the appropriate Tissue Specific preset.
3. Select **Biopsy On** from the **2D/MMode** menu.


4. Immerse the scanhead no more than 0.64 cm (0.25 inch) into the water bath, and insert the needle into the biopsy guide (Figure 5–3).
5. Move the needle down into the water bath until its ultrasound image is visible on the video display.

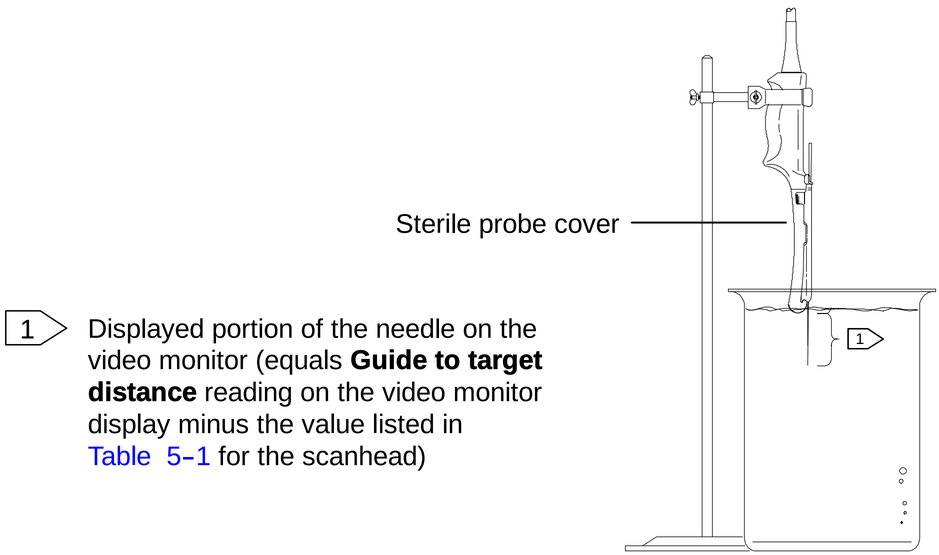


Figure 5–3. Guide to Target Distance

WARNING

IIf the needle enters from the unexpected side of the display, verify that the biopsy guide is correctly mounted and that the orientation of the scanhead is correct. If the needle is still not following the expected path along the guideline, *do not use* the biopsy guide. Contact your ATL customer service representative.

6. Verify that the needle, as seen on the video display, falls along the guideline along the entire depth of the guideline display. The biopsy guideline is only intended to provide an indication of the expected path of the needle. Actual position must be verified by identifying the echoes from the needle.
7. Remove the needle from the biopsy guide.
8. Move the depth cursor to the **Guide to target distance** for the scanhead as listed in Table 5–1.
9. From the tip of the needle, measure a distance equal to the **Guide to target distance** value noted in step 8. Mark this point on the needle.
10. Immerse the scanhead no more than 0.64 cm (0.25 inch) into the water bath.

11. Insert the needle into the biopsy guide until the mark on the needle aligns with the origin on the biopsy guide (Figure 5-4). (The origin is the point at which the needle enters the biopsy guide or needle insert.)
12. Verify that the tip of the needle, as seen on the video display, falls within the range listed in Table 5-1.
13. Confirm that the needle is visible along its expected path. If so, then the biopsy guide is properly aligned.

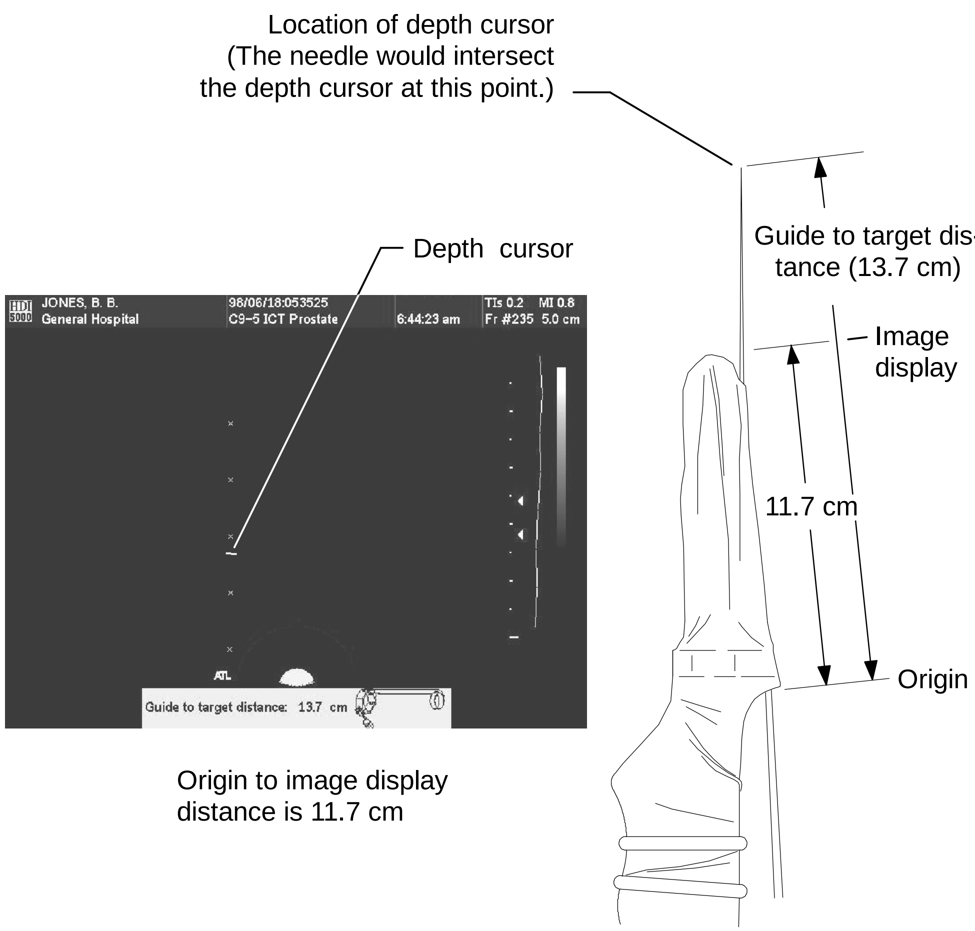


Figure 5-4. Biopsy Guide Depth and Distance Relationships Example: C9-5 Scanhead and Biopsy Guide

Table 5-1. Guide to Target Distances and Ranges

Scanheads	Distance and Range
C4–2	11.8 cm ± 0.50 cm
C5–2	11.8 cm ± 0.50 cm
C7–4	11.9 cm ± 0.50 cm
C8-5	6.7 cm ± 0.50 cm
C9–5 ICT	13.7 cm ± 0.50 cm
C8–4v IVT	19.8 cm ± 0.50 cm
L7–4	8.0 cm ± 0.50 cm
L10–5	8.0 cm ± 0.50 cm
L12–5 38 mm	6.4 cm ± 0.50 cm
L12–5 50 mm	6.4 cm ± 0.50 cm
P4–2	11.6 cm ± 0.50 cm
P5–3	8.8 cm ± 0.50 cm
P6–3	8.8 cm ± 0.50 cm
P7–4	9.4 cm ± 0.50 cm

Needle/Scan Plane Verification for the L12–5 50 mm

WARNINGS

- Verifying that the needle appears in the scan plane is necessary prior to performing procedures with the L12–5 50 mm biopsy guide.
- Do not use the biopsy guide if the needle does not appear where you expect.
- The needle used for this verification must not be used for the actual procedure. Always use a new, sterile needle for each biopsy procedure.
- To assist in an accurate projection of the needle, use a straight, new needle for each verification procedure.

To verify that the needle appears in the scan plane:

1. Prepare a water bath. A beaker filled with water is sufficient.
2. Install the probe cover and biopsy guide on the scanhead.


3. Connect the scanhead to the system, and select the appropriate Tissue Specific preset.
4. Immerse the scanhead no more than 0.64 cm (0.25 inch) into the water bath, and insert the needle into the biopsy guide.
5. Move the needle down into the water bath until the needle is visible in the scan plane on the display.
6. Confirm that the needle enters the display at the point you expect.

WARNING

If the needle enters the display at a different position than you expected, verify that the biopsy guide is correctly mounted and that the orientation of the scanhead is correct. If the needle is still not appearing where you expect, *do not use* the biopsy guide. Contact your ATL Customer Service representative.

Biopsy Procedure

WARNINGS

- Alignment verification should be performed at the selected depth prior to the biopsy procedure to ensure that the biopsy guide and the needle have been installed properly.
- Thin needles can bend when entering tissue. Actual position must be verified by identifying the echoes from the needle.
- ATL does not recommend anatomical survey of the prostate with the biopsy guide attached.
- Use a straight, new needle for each procedure.
- The biopsy guideline is only intended to provide an indication of the expected path of the needle. Actual position must be verified by identifying the echoes from the needle.
- If the needle is not following the expected path, discontinue the procedure and contact an ATL Customer Service representative.

" **To perform a biopsy procedure:**

1. Install the probe cover and the biopsy guide.
2. Set the system controls for the biopsy procedure.
3. Orient the scanhead to match the image presentation. Use the 2D scan plane orientation marker.
4. Apply sterile, water-based lubricant to the probe cover, as needed.
5. Begin scanning the patient. Maneuver the scanhead so that the puncture target falls along the guideline displayed on the system monitor.

6. Perform the procedure by sliding the needle through the biopsy guide until the needle, as depicted by the echoes on the display, meets the target.

Biopsy Guide Maintenance

WARNING

The procedure kit components are disposable and must not be reused.

CAUTION

Before cleaning, disinfecting, or sterilizing the biopsy guide or the transition wedge, refer to *Using Disinfectants and Gels*, ATL part number 4700-0249, -16 or higher.

Probe Covers

Probe covers are recommended for clinical applications of an invasive nature, including intraoperative, transrectal, intravaginal, transesophageal, and biopsy procedures. ATL recommends the use of ATL-qualified probe covers. You can order probe covers from ATL Supplies and Accessories or your local ATL representative.

WARNING

Some probe covers contain natural rubber latex and talc, which may cause allergic reactions in some individuals. Refer to the FDA Medical Alert, March 29, 1991, reprinted here.

FDA Medical Alert, March 29, 1991, Allergic Reactions to Latex-Containing Medical Devices

Because of reports of severe allergic reactions to medical devices containing latex (natural rubber), the FDA is advising health care professionals to identify their latex sensitive patients and be prepared to treat allergic reactions promptly. Patient reactions to latex have ranged from contact urticaria to systemic anaphylaxis. Latex is a component of many medical devices, including surgical and examination gloves, catheters, intubation tubes, anesthesia masks, and dental dams.

Reports to the FDA of allergic reactions to latex-containing medical devices have increased lately. One brand of latex cuffed enema tips was recently recalled after several patients died as a result of anaphylactoid reactions during barium enema procedures. More reports of latex sensitivity have also been found in the medical literature. Repeated exposure to latex both in medical devices and in other consumer products may be part of the reason that the prevalence of latex sensitivity appears to be increasing. For example, it has been reported that 6% to 7% of surgical personnel and 18% to 40% of spina bifida patients are latex sensitive.

Proteins in the latex itself appear to be the primary source of the allergic reactions. Although it is not now known how much protein is likely to cause severe reactions, the FDA is working with manufacturers of latex-containing medical devices to make protein levels in their products as low as possible.

FDA's recommendations to health professionals in regard to this problem are as follows:

- When taking general histories of patients, include questions about latex sensitivity. For surgical and radiology patients, spina bifida patients and health care workers, this recommendation is especially important. Questions about itching, rash or wheezing after wearing latex gloves or inflating a toy balloon may be useful. Patients with positive histories should have their charts flagged.

- If latex sensitivity is suspected, consider using devices made with alternative materials, such as plastic. For example, a health professional could wear a non-latex glove over the latex glove if the patient is sensitive. If both the health professional and the patient are sensitive, a latex middle glove could be used. (Latex gloves labeled “Hypoallergenic” may not always prevent adverse reactions.)
- Whenever latex-containing medical devices are used, especially when the latex comes in contact with mucous membranes, be alert to the possibility of an allergic reaction.
- If an allergic reaction does occur and latex is suspected, advise the patient of a possible latex sensitivity and consider an immunologic evaluation.
- Advise the patient to tell health professionals and emergency personnel about any known latex sensitivity before undergoing medical procedures. Consider advising patients with severe latex sensitivity to wear a medical identification bracelet.

The FDA is asking health professionals to report incidents of adverse reactions to latex or other materials used in medical devices. (See the October 1990 FDA Drug Bulletin.) To report an incident, call the FDA Problem Reporting Program, operated through the U.S. Pharmacopeia toll-free number: 800-638-6725. (In Maryland, call collect 301-881-0256.)

For a single copy of a reference list on latex sensitivity, write to: LATEX, FDA, HFZ-220, Rockville, MD 20857.

WARNINGS

S If the sterile cover becomes compromised during surgical applications involving a patient with Creutzfeldt-Jakob disease, the scanhead cannot be sterilized or adequately disinfected by any method.

S Covers are disposable and must not be reused.

S In neurological applications, sterilized scanheads should be used with a pyrogen-free probe cover.

S If an installed cover is cut or contaminated before use, a new cover must be installed.

Installing the Cover

A cover is recommended for some ultrasound procedures, including intracavity, surgical, and biopsy procedures. The basic installation is described in the following procedure.

" **To install the cover:**

1. Wearing sterile gloves and without unrolling the cover, remove the cover from its package.
2. Refer to the figure of the type of scanhead and cover you are using, and fill the cover with sterile acoustic coupling gel as shown in the appropriate figure (Figure 6–1 and Figure 6–2).

3. Insert the tip of the scanhead into the center of the rolled cover, and then unroll or pull the cover to completely cover the scanhead, and if appropriate, the scanhead cable (Figure 6–3 through Figure 6–4).

WARNING Maintain the sterility of the cover.

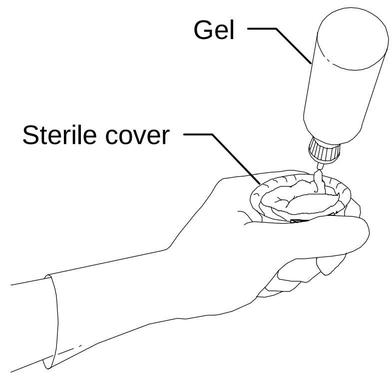


Figure 6–1. Applying Gel to a Cover: Example

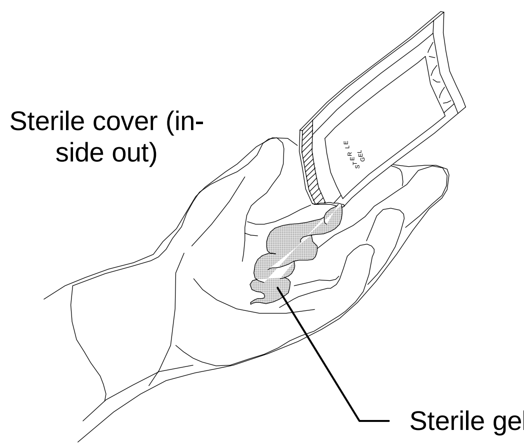


Figure 6–2. Applying the Gel to a Cover: Example

4. Pull the tip of the sterile cover snugly over the scanhead ensuring there are no air bubbles in the acoustic gel on the face of the array.

5. Secure the cover to the scanhead, and if appropriate, the scanhead cable (Figure 6–3 through Figure 6–5). A securing O-ring is not required if a biopsy guide is installed over the cover on the scanhead.

6. After the exam, dispose of the cover.

CAUTION

The tape strips are very strong. To remove them, carefully cut the tape with blunt–end scissors. Do not use scalpels or other sharp instruments that will damage the cable or scanhead.

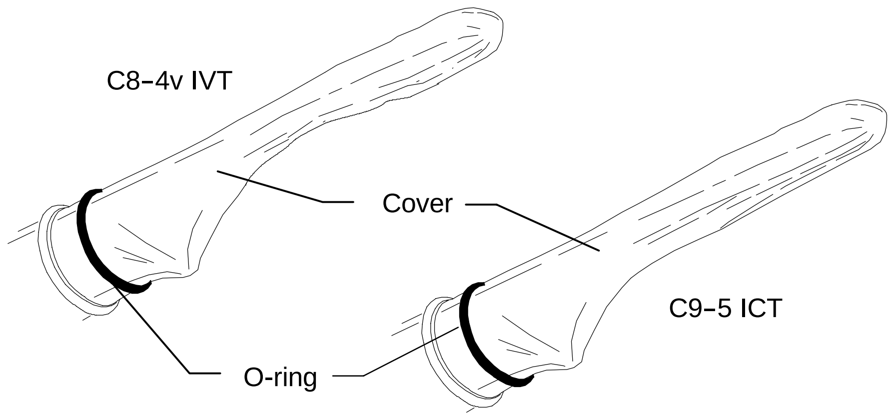


Figure 6–3. Intracavity Scanheads with Sterile Cover

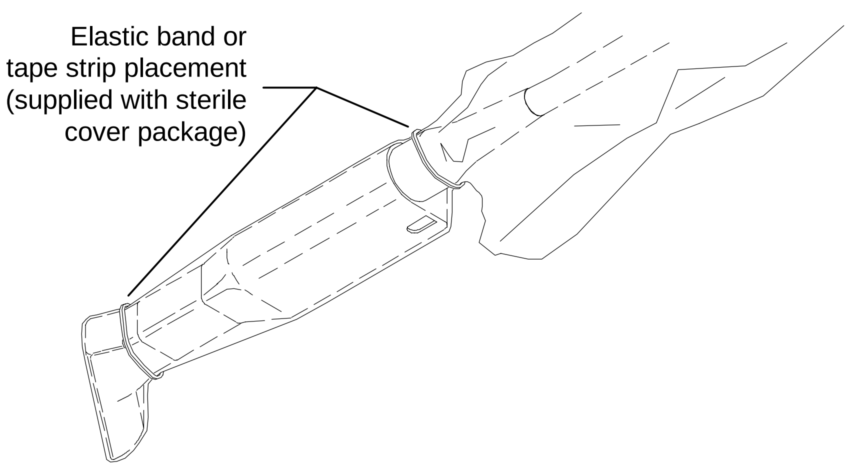


Figure 6–4. Securing the Sterile Cover to a Scanhead: Example

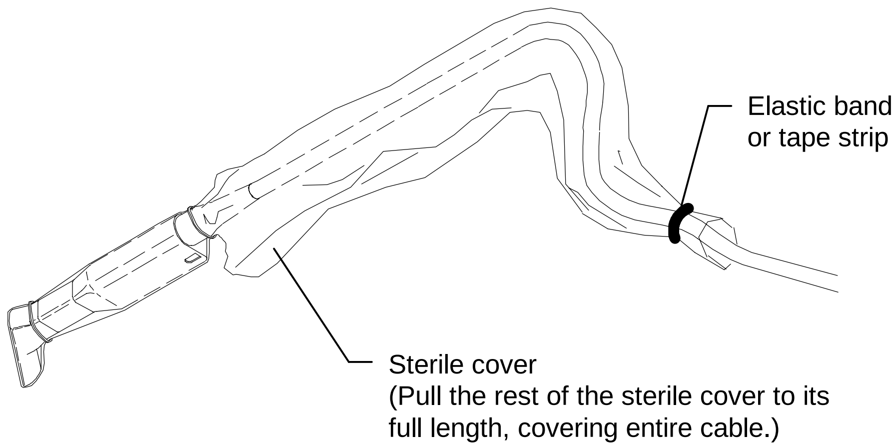


Figure 6-5. Securing the Sterile Cover to the Scanhead Cable: Example

Installing Covers on the LAP L9-5

Two covers are recommended for the laparoscopic scanhead: one for the laparoscope, and one for the control housing and cable.

WARNINGS

S The cover is disposable and must not be reused.

S If the cover is cut before use, a new cover must be installed.

" **To install the covers:**

1. Wearing gloves, remove the first cover from its package.
2. Insert sterile acoustic coupling gel into the first cover using a sterile syringe. The first cover can be filled with sterile saline solution instead of gel, if desired.
3. Insert the tip of the scanhead into the center of the cover, and pull the cover over the laparoscope.
4. Pull the latex tip of the sterile cover snugly over the scanhead ensuring there are no air bubbles in the acoustic gel on the face of the array.
5. If saline solution is used, secure the cover using a suture string (Figure 6-6).

WARNING

Maintain the sterility of the cover.

6. Position the second cover over the control housing and the cable, and secure it with an elastic band (Figure 6-6).

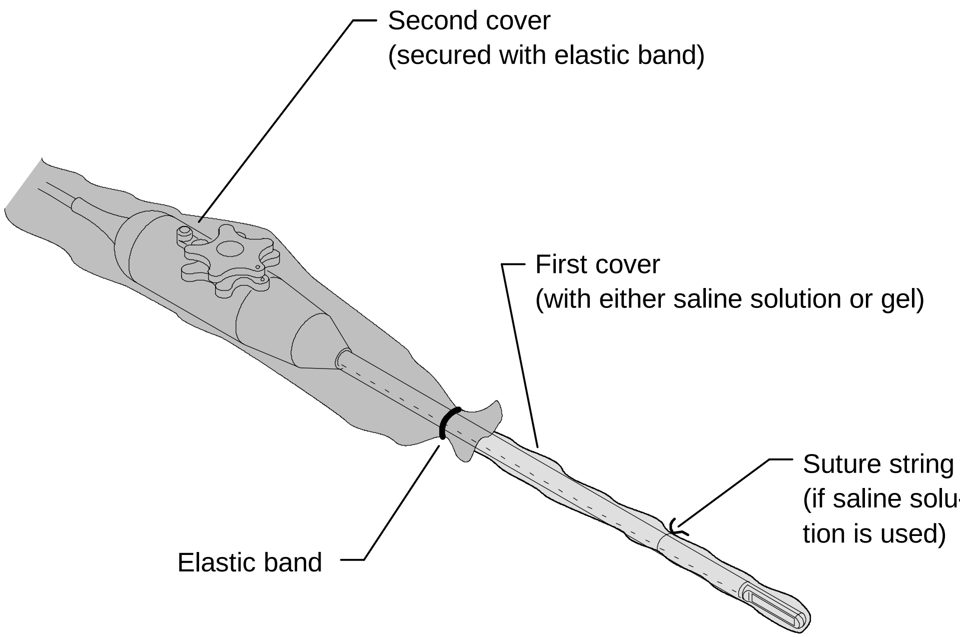


Figure 6-6. Laparoscopic Scanhead with Sterile Covers

Safety

Please read this information before using an ATL ultrasound system. It applies to the ultrasound system, scanheads, recording devices, and any optional equipment.

This device is intended for use by, or by the order of, and under the supervision of a licensed physician qualified to direct the use of the device.

In this manual set, a **WARNING** describes precautions necessary to prevent injury or loss of life.

In this manual set, a **CAUTION** describes precautions necessary to protect the equipment.

Electrical Safety

This equipment has been certified by a recognized third-party testing agency as a Class I device with Type B non-isolated and Type BF and Type CF isolated patient-applied parts. For maximum safety observe these warnings:

WARNINGS

- Shock hazards may exist if this system, including all externally mounted recording and monitoring devices, is not properly grounded. Protection against electrical shock is provided by grounding the chassis with a three-wire cable and plug. The system must be plugged into a grounded outlet. The grounding wire must not be removed or defeated.
- Do not remove the protective covers on the system; hazardous voltages are present inside. Cabinet panels must be in place while the system is in use. All internal adjustments and replacements must be made by a qualified ATL Customer Service Representative.
- Do not operate this system in the presence of flammable gases or anesthetics. Explosion can result.
- To avoid risk of electrical shock hazards, always inspect the scanhead, pencil probe, pulse transducer, and phonocardiography transducer before use: check the face, housing, and cable before use. Do not use it, if the face is cracked, chipped, or torn, the housing is damaged, or the cable is abraded.
- Inspect the Digital Video Streaming (DVS) hand controller before use. Do not use it, if the housing or the cable is damaged.
- Inspect the Advanced 3DI Position Sensor and cable before use. Do not use it, if the position sensor or the cable is damaged.
- To avoid risk of electrical shock hazards, always disconnect the system from the wall outlet prior to cleaning the system.

WARNINGS

- All patient contact devices, such as scanheads, pencil probes, pulse transducers, phonocardiography transducers, and ECG leads must be removed from patient contact prior to application of a high voltage defibrillation pulse.
- Connection of optional devices not supplied by ATL could result in electrical shock. When such optional devices are connected to your ultrasound system, ensure that the total system earth leakage current does not exceed 300 μA.
- To avoid risk of electrical shock, do not use any scanhead or probe that has been immersed beyond the specified cleaning or disinfection level. See *Using Disinfectants and Gels*, part number 4700-0249, -16 or higher.
- To avoid risks of electrical shock and fire hazards, inspect the system power cord and plug on a regular basis. Ensure that they are not damaged in any way.


CAUTIONS

- Prior to connecting the system to a power outlet, verify the voltage and frequency of the power outlet.
- Although your system has been manufactured in compliance with existing EMI/EMC requirements, use of this system in the presence of an electromagnetic field can cause momentary degradation of the ultrasound image. If this occurs often, ATL suggests a review of the environment in which the system is being used, to identify possible sources of radiated emissions. These emissions could be from other electrical devices used within the same room or an adjacent room. Communication devices such as cellular phones and pagers can cause these emissions. The existence of radio, TV, or microwave transmission equipment located nearby can cause emissions. In cases where EMI is causing disturbances, it may be necessary to relocate your system.
- Electrostatic discharge (ESD), commonly referred to as a static shock, is a naturally occurring phenomenon. ESD is most prevalent during conditions of low humidity, which can be caused by heating or air conditioning. During low humidity conditions, electrical charges naturally build up on individuals and can create static shocks. An ESD condition occurs when an individual with an electrical energy build-up comes in contact with objects such as metal doorknobs, file cabinets, computer equipment, and even other individuals. The static shock or ESD is a discharge of the electrical energy build-up from a charged individual to a lesser or non-charged individual or object. The level of electrical energy discharged from a system user or patient to the ultrasound system can be significant enough to cause damage to the system or scanheads.
- The following precautions can help to reduce ESD: anti-static spray on carpets; anti-static spray on linoleum; anti-static mats; or a ground wire connection between the system and the patient table or bed. Additionally, any build-up of electrical energy can be dissipated by first touching the gray, rubber ESD pads provided on the system handles and wrist support of the system keyboard, before using the system (Figure 7-1).

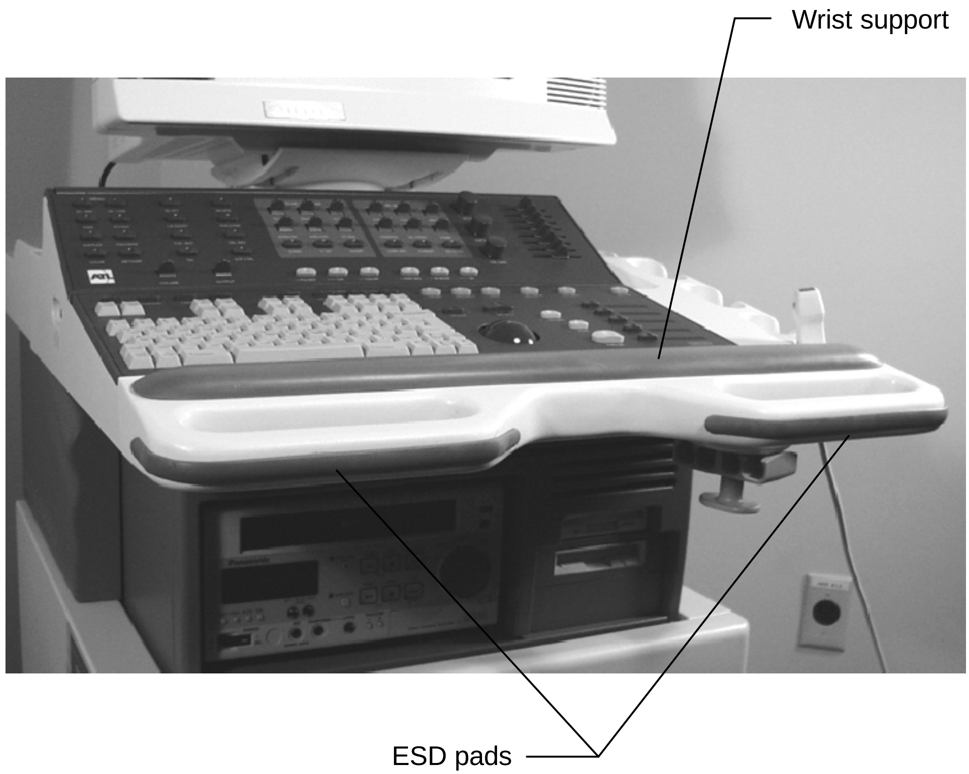


Figure 7-1. Locations of the Wrist Support and ESD Pads

Mechanical Safety

WARNINGS

- Be aware of the casters, especially when moving the system. The system can weigh 200 kg (440 pounds), depending upon configuration, and it could cause injury to you or others if it rolls over feet or into shins. ATL recommends that you exercise caution when going up or down ramps.
- Position external hardcopy devices away from the system. Ensure that they are secure. Do not stack them on the system.
- The monitor has been designed so that it can be easily removed from the system if needed. While using the system, or transporting the system with the monitor on the system, ensure that the two monitor latches are in the forward-horizontal, “locked” position.

CAUTION

Ensure that the cables for all patient-applied parts are secure. Use the cable management system to ensure that scanhead cables are protected from damage.

System Brakes

The system has brakes for the front and the rear wheels. Push back with your foot on a brake to lock it, and pull forward to release it. Release the brakes when you move the system.

Moving the System

The front and back wheels are steerable on the system. If the system operates abnormally after you move it, contact ATL Ultrasound Customer Service immediately. The components are installed securely and can withstand considerable shock, but excessive shock can cause a system failure.

Equipment Protection

Follow these precautions to protect your system:

CAUTIONS

- Excessive bending or twisting of cables on patient-applied parts may cause failure or intermittent operation of the system.
- Improper cleaning or sterilization of a patient-applied part may cause permanent damage. For cleaning and disinfection instructions, see *Using Disinfectants and Gels*, part number 4700-0249,-16 or higher.
- Do not submerge the cables of patient-applied parts in solution. The cables are not liquid-tight beyond the applied part/cable or cable/connector interfaces.

CAUTIONS

- Systems designed for connection to 230 or 240 Vac power have both 120 Vac and 240 Vac available for the installed hardcopy devices. The 120 Vac is provided for the monitor, and the 240 Vac for the VCR and printer. Prior to connecting an OEM power cord, verify that the voltage indicated on the power cord matches the voltage rating of the OEM device.
- Do not use solvents such as thinner or benzine, or abrasive cleaners on the system, scanhead or any hardcopy device.
- For optimal performance, your ATL ultrasound system should be connected to a circuit dedicated solely for the HDI 5000 system.
- An isolation transformer protects the system from power surges. The isolation transformer continues to operate when the system is in standby. Ensure that the circuit breaker is off, before unplugging the system from the wall outlet.
- In general, only the area of the scanhead acoustic window is watertight. Except where specified in specific scanhead cleaning instructions, do not immerse the remainder of a scanhead in any liquid.

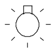
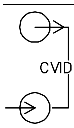
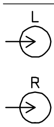
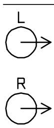
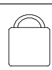
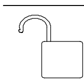

Symbols

The International Electrotechnical Commission (IEC) has established a set of symbols for medical electronic equipment which classify a connection or warn of potential hazards. The classifications and symbols are shown below.

	Non-isolated patient connection. (Type B)
	Isolated patient connection. (Type BF)
	Isolated patient connection for applied parts in direct contact with major vessels. (Type CF)
I / O	On the circuit breaker, represents ON and OFF.
/	On the ON/STANDBY switch, represents ON and STANDBY.
	This symbol identifies a safety note. Ensure you understand the function of this control before using it. Refer to the appropriate section in the *Reference Manual* for an explanation of the control.
	Identifies equipotential ground.
IPX1	Indicates that this device is protected against dripping water. This degree of protection can apply to scanheads and footswitches.
IPX7	Indicates that this device is protected against the effects of immersion. This degree of protection can apply to scanheads.

The following symbols are also used on the system:

	Connection for a pencil probe.
	Connection for a scanhead.
	Connection for ECG.
/ **A**	Connection for pulse transducer.
/ **B**	Connection for phono transducer.
	Connection for footswitch.
	Monitor brightness control.


	Monitor contrast control.
	Color background control.
	Lightbar control.
	Microphone.
NI–RGBS	Non-interlaced RGB video with separate composite sync.
I–RGB	Interlaced RGB video with separate composite sync.
SVID	S video NTSC/PAL video output and input.
	Composite NTSC/PAL video output and input.
B&W VID	Composite monochrome video.
	Serial and parallel printer connection. Parallel printer not supported.
10101 SERIAL	Serial output connection.
E–NET	Ethernet connection.
	Left and right audio input.
	Left and right audio output.
	DVS hand-controller connection.
	Lock.
	Unlock.

The following symbols are used inside the system:

	Identifies high voltage components.
	Ground.


Biological Safety

This section contains information about biological safety and a discussion of the prudent use of the system.

A list of precautions related to biological safety follows; observe these precautions when using the system. For more information refer to 4700-0263-01*, Medical Ultrasound Safety*.

WARNINGS

- Do not use the system if an error message appears on the video display indicating that a hazardous condition exists. Note the error code, turn off power to the system, and call your ATL Customer Service Representative.
- Do not use a system that exhibits erratic or inconsistent updating. Discontinuities in the scanning sequence are indicative of a hardware failure that must be corrected before use.
- Perform ultrasound procedures prudently. Use the ALARA (as low as reasonably achievable) principle.
- Use only acoustic standoffs that have been approved for use by ATL.
- Verify the alignment of the biopsy guide before use. See the "Biopsy Guides" section of this manual.
- Verify the condition of the biopsy needle before use. Do not use a bent biopsy needle.
- Biopsy guide probe covers may contain natural rubber latex. These covers may cause allergic reactions in some individuals. Refer to the FDA Medical Alert on Latex Products, dated March 29, 1991, in the "Probe Covers" section of this manual.
- For transcranial or cephalic use: when imaging or conducting pulsed Doppler and color flow studies, this device is only intended for use in adults with intact skulls through the temporal and suboccipital windows.
- This device is not intended for use through the orbital window, burrholes, craniotomies, or neonatal fontanelles.
- Avoid scanning the posterior orbit of the eye. For transcranial or cephalic use: when scanning in the posterior region of the orbits, please be advised that this device exceeds the FDA acoustic power and intensity limits for ophthalmic scanning.

ALARA Education Program

The guiding principle for the use of diagnostic ultrasound is defined by the "as low as reasonably achievable" (ALARA) principle. The decision as to what is reasonable has been left to the judgement and insight of qualified personnel. No set of rules can be formulated that would be sufficiently complete to dictate the correct response to every circumstance.

By keeping ultrasound exposure as low as possible, while obtaining diagnostic images, users can minimize ultrasonic bioeffects.

Since the threshold for diagnostic ultrasound bioeffects is undetermined, it is the sonographer's responsibility to control total energy transmitted into the patient. The sonographer must reconcile exposure time with diagnostic image quality. To ensure diagnostic image quality and limit exposure time, an ultrasound system provides controls that can be manipulated during the exam to optimize the results of the exam.

The ability of the user to abide by the ALARA principle is important. Advances in diagnostic ultrasound not only in the technology but in the applications of that technology, have resulted in the need for more and better information to guide the user. The output display indices are designed to provide that important information.

There are a number of variables which affect the way in which the output display indices can be used to implement the ALARA principle. These variables include indice values, body size, location of the bone relative to the focal point, attenuation in the body, and ultrasound exposure time. Exposure time is an especially useful variable, because it is controlled by the user. The ability to limit the index values over time supports the ALARA principle.

Applying ALARA

The system imaging mode used depends upon the information needed. 2D and M-Mode imaging provide anatomical information, while Doppler, Power, and Color imaging provide information about blood flow. A scanned mode, like 2D, Power, or Color, disperses or scatters the ultrasonic energy over an area, while an unscanned mode, like M-Mode or Doppler, concentrates ultrasonic energy. Understanding the nature of the imaging mode being used allows the sonographer to apply the ALARA principle with informed judgement. Additionally, the scanhead frequency, system setup values, scanning techniques, and operator experience allow the sonographer to meet the definition of the ALARA principle.

The decision as to the amount of acoustic output is, in the final analysis, up to the system operator. This decision must be based on the following factors: type of patient, type of exam, patient history, ease or difficulty of obtaining diagnostically useful information, and the potential localized heating of the patient due to scanhead surface temperatures. Prudent use of the system occurs when patient exposure is limited to the lowest index reading for the shortest amount of time necessary to achieve acceptable diagnostic results.

Although a high index reading does not mean that a bioeffect is actually occurring, a high index reading should be taken seriously. Every effort should be made to reduce the possible effects of a high index reading, limiting exposure time is an effective way to accomplish this goal.

There are several system controls that the operator can use to adjust the image quality and limit the acoustic intensity. These controls are related to the techniques that an operator might use to implement ALARA. These controls can be divided into three categories: direct, indirect, and receiver controls.

Direct Controls

Application selection and the output intensity control directly affect acoustic intensity. Application selection refers to your selection of a clinical option and a Tissue Specific preset. There are different ranges of allowable intensity or output based on your selection. Selecting the correct range of acoustic intensity for the application is one of the first things that occurs in any exam. For example, peripheral vascular intensity levels are not recommended for fetal exams. Some systems automatically select the proper range for a particular application, while others require manual selection. Ultimately, the user has the responsibility for proper clinical use. The ATL system provides both automatic or default and manual or user-selectable settings.

Output has direct impact on acoustic intensity. Once the application has been established, the output control can be used to increase or decrease the intensity output. The output control allows you to select intensity levels less than the established maximum. Prudent use dictates that you select the lowest output intensity that is consistent with good image quality.

Indirect Controls

The indirect controls are those that have an indirect effect on acoustic intensity. These controls affect imaging mode, pulse repetition frequency, focus depth, pulse length, and scanhead selection.

The choice of imaging mode determines the nature of the ultrasound beam. 2D is a scanning mode, Doppler is a stationary or unscanned mode. A stationary ultrasound beam concentrates energy in a single location. A moving or scanned ultrasound beam disperses the energy over an area and the beam is concentrated on the same area for a fraction of the time as that of an unscanned mode.

Pulse repetition frequency or rate refers to the number of ultrasound bursts of energy over a specific period of time. The higher the pulse repetition frequency, the more pulses of energy in a period of time. Several controls affect pulse repetition frequency: focal depth, display depth, sample volume depth, color sensitivity, number of focal zones, and sector width controls.

Different exams require different focal depths. Setting the focus at the proper depth improves the resolution of the structure of interest. Changing the focus can affect the acoustic output.


Pulse length is the time during which the ultrasonic burst is turned on. The longer the pulse, the greater the time-average intensity value. The greater the time-average intensity, the greater the likelihood of temperature increase and cavitation. Increasing the Doppler sample volume increases the pulse length.

Scanhead selection indirectly affects intensity. Tissue attenuation changes with frequency. The higher the scanhead operating frequency, the greater the attenuation of the ultrasonic energy. To scan deeper at the same output intensity, a lower scanhead frequency is required. Using more gain and output beyond a point, without corresponding increases in image quality, can mean that a lower frequency scanhead is needed.

Receiver Controls

Receiver controls are used by the operator to improve image quality. These controls have no effect on output. Receiver controls only affect how the ultrasound echo is received. These controls include gain, TGC, dynamic range, and image processing. The important thing to remember, relative to output, is that receiver controls should be optimized before output is increased. For example: before increasing output, optimize gain to improve image quality.

An Example of Applying ALARA

An ultrasound scan of a patient's liver begins with selecting the appropriate scanhead frequency. After selecting the scanhead, clinical option, and Tissue Specific preset, which are based on patient anatomy, adjustments to output power should be made to ensure that the lowest possible setting is used to acquire an image. After the image is acquired, adjusting the focus of the scanhead, and then increasing the receiver gain to produce a uniform representation of the tissue follows. If an adequate image can be obtained with the increase in gain, then a decrease in output should be made. Only after making these adjustments should you increase output to the next level.

Having acquired the 2D display of the liver, Color can be used to localize blood flow. As with the 2D image display, gain and image processing controls must be optimized before increasing output.

Having localized the blood flow, use the Doppler controls to position the sample volume over the vessel. Before increasing output, adjust velocity range or scale and Doppler gain to obtain an optimal Doppler trace. Only if maximum Doppler gain does not create an acceptable image do you increase output.

In summary: select the correct transducer frequency and application for the job; start with a low output level; optimize the image using focus, receiver gain, and other imaging controls; if the image is not diagnostically useful at this point, then increase output.

Additional Considerations

Ensure that scanning time is kept to a minimum, and ensure that only medically required scanning is performed. Never compromise quality by rushing through an exam. A poor exam may require a follow-up, which ultimately increases exposure time. Diagnostic ultrasound is an important tool in medicine, and, like any tool, it should be used efficiently and effectively.

Output Display

The system output display comprises two basic indices: a mechanical index (MI)and a thermal index. The thermal index further consists of three indices: soft tissue (TIs), cranial bone (TIc), and bone (TIb). One of these three thermal indices will be displayed at all times. Which one depends upon the system preset or user choice, depending upon the application at hand.

The MI is continuously displayed over the range of 0.0 to 1.9, in increments of 0.1.

The TI consists of the three indices, and only one of these is displayed at any one time. Each scanhead application has a default selection that is appropriate for that combination. The TIb, TIc, or TIs is continuously displayed over the range of 0.0 to 6.0 in increments of 0.1.

The application-specific nature of the default setting is also an important factor of index behavior. A default setting is a system control state which is preset by the manufacturer or the operator. The system has default index settings for the scanhead application. The default settings are invoked automatically by the ultrasound system when power is turned on, new patient data is entered into the system data base, or a change in application takes place.

Figure 7–2 illustrates the implementation of the output display in the system.

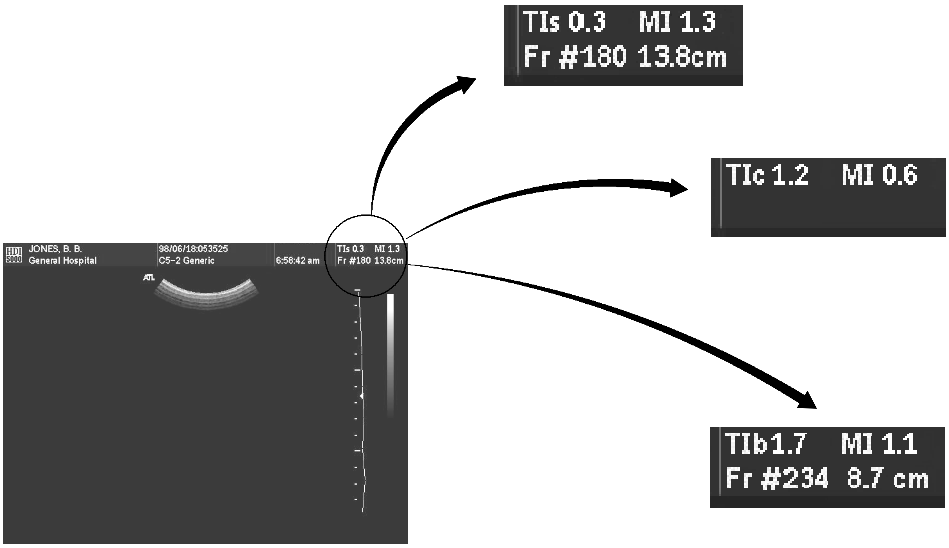


Figure 7-2. On-Screen TI and MI

The decision to display one or the other of the three thermal indices should be based on the following criteria:

- Appropriate index for the application: TIs is used for imaging soft tissue; TIc for transcranial; and TIb for a focus at or near bone.
- Mitigating factors that might create artificially high or low thermal index readings: location of fluid or bone, or blood flow. For example, is there a highly attenuating tissue path so that the actual potential for local zone heating is less than the thermal index displays.
- Scanned modes versus unscanned modes of operation affect the thermal index. For scanned modes, heating tends to be near the surface; for unscanned modes, the potential for heating tends to be deeper in the focal zone.
- Always limit ultrasound exposure time. Do not rush the exam. Ensure that the indices are kept to a minimum and that exposure time is limited without compromising diagnostic sensitivity.

Mechanical Index Display

Mechanical bioeffects are threshold phenomena that occur when a certain level of output is exceeded. The threshold level varies, however, with the type of tissue. The potential for mechanical bioeffects varies with peak pressure and ultrasound frequency. The mechanical index accounts for these two factors. The higher the mechanical index value, the greater the likelihood of mechanical bioeffects occurring. There is no specific mechanical index value at which a mechanical effect actually occurs. The mechanical index should be used as a guide for implementing the ALARA principle.

Thermal Index Displays

The TI informs the user about the conditions that exist that might lead to an increase in temperature at the surface of the body, within the body tissue, or at the point of focus of the ultrasound beam on bone. That is, the TI informs the user of the potential for temperature rise in body tissue. The TI is an estimate of temperature increase in body tissue with specific properties. The actual amount of any temperature rise is influenced by such factors as tissue type, vascularity, mode of operation, and others. The TI should be used as a guide for implementing the ALARA principle.

The soft tissue TI (TIs) informs the user about the potential for heating within soft homogeneous tissue.

The cranial bone TI (TIc) informs the user about the potential heating of bone at or near the surface, for example, cranial bone.

The bone TI (TIb) informs the user about potential heating at or near the focus after the ultrasound beam has passed through soft tissue or fluid, for example, at or near second or third trimester fetal bone.

Mechanical and Thermal Indices Precision and Accuracy

The displayed values should be interpreted as relative information to help the system operator achieve the ALARA principle through prudent use of the system. The values should not be interpreted as actual physical values in interrogated tissue or organs. The initial data that is used to support the output display is derived from laboratory measurements based on the AIUM measurement standard. The measurements are then put into algorithms for calculating the displayed output values.

Many of the assumptions used in the process of measurement and calculation are conservative in nature. Over-estimation of actual in situ intensity exposure, for the vast majority of tissue paths, is built into the measurement and calculation process; for example:

- The measured water tank values are derated using a conservative, industry standard attenuation coefficient of 0.3 dB/cm–MHz.
- Conservative values for tissue characteristics were selected for use in the TI models. Conservative values for tissue or bone absorption rates, blood perfusion rates, blood heat capacity, and tissue thermal conductivity were selected.

- Steady state temperature rise is assumed in the industry standard TI models, and the assumption is made that the ultrasound scanhead is held steady in one position long enough for steady state to be reached.

A number of factors are considered when estimating the accuracy of the displayed values; primary among them are hardware variations, estimation algorithm accuracy, and measurement variability. Variability among scanheads and systems is a significant factor. Scanhead variability is a product of, among others: the variability in piezoelectric crystal efficiencies, process-related impedance differences, and sensitive lens focusing parameter variations. Differences in system pulser voltage control and efficiencies is a contributor to variability, though in general, system variability tends to be smaller than scanhead variability. There are inherent uncertainties in the algorithms used to estimate acoustic output values over the very large range of possible system operating conditions and pulser voltages. Inaccuracies in laboratory measurements are related to, among others, differences in hydrophone calibration and performance; positioning, alignment, and digitization tolerances; and variability among test operators.

The conservative assumptions of the output estimation algorithms of linear propagation, at all depths, through a 0.3 dB/cm–MHz attenuative medium is not considered in the accuracy estimate for the display. Neither linear propagation nor uniform attenuation at the 0.3 dB/cm–MHz rate occur in water tank measurements or in most tissue paths in the body. In the body, different tissues and organs have dissimilar attenuation characteristics. In water, there is almost no attenuation. In the body, and in particular in water tank measurements, non-linear propagation and saturation losses occur as pulser voltages increase.

Therefore, the display accuracy estimates are based on the variability range of scanheads and systems, inherent acoustic output modeling errors, and measurement variability. Display accuracy estimates are not based on errors in, or caused by, measuring according to the AIUM measurement standards or the effects of non-linear loss on the measured values.

Thermal Index Help

The system provides an on-screen help feature. Press **TI Help** to access this feature. Pressing **TI Help** displays a summary of the information contained in this section.

You can select either TIs or TIb using the **TIs/TIb** selection on the **2D/MMode** menu or by pressing the **Superkey** and the **TI** key on the system keyboard. TIc is displayed when you select a transcranial application.

Control Effects

Controls Affecting the Indices

As various system controls are adjusted, the TI and MI values may change. This will be most apparent as the **OUTPUT** control is adjusted; however, other system controls will affect the on-screen output values. The following information supplements the **TI Help** function.

OUTPUT

OUTPUT controls the system acoustic output. Two real-time output values are on the screen: a thermal index and a mechanical index. They change as the system responds to **OUTPUT** control adjustments.

In combined modes, such as simultaneous Color, 2D and pulsed Doppler, the individual modes each add to the total thermal index. One mode will be the dominant contributor to this total. The displayed MI will be from the mode with the largest peak pressure.

2D Controls

Sector Angle

Narrowing the sector angle may increase frame rate. This action will increase the thermal index. Pulser voltage may be automatically adjusted down with software controls to keep the thermal index below the system maximums. A decrease in pulser voltage will decrease MI.

ZOOM and HD ZOOM

Increasing the zoom magnification may increase frame rate. This action will increase the thermal index. The number of focal zones may also increase automatically to improve resolution. This action may change MI since the peak intensity can occur at a different depth.

Frame Rate

A lower frame rate will decrease the thermal index. Pulser voltage may be automatically increased. An increase in pulser voltage will increase MI.

ZONES

More focal zones may change both the thermal index and MI by changing frame rate or focal depth automatically. Lower frame rates decrease the thermal index. MI displayed will correspond to the zone with the largest peak intensity.

FOCUS

Changing the focal depth will change MI. Generally, higher MI values will occur when the focal depth is near the natural focus of the transducer.

Color and Power Controls

Color Sensitivity

Increasing the color sensitivity may increase the thermal index. More time is spent scanning the color image. Color pulses are the dominant pulse type in this mode.

Color Sector Width

Narrower color sector width will increase color frame rate and the thermal index will increase. The system may automatically decrease pulser voltage to stay below the system maximum. A decrease in pulser voltage will decrease the MI. If pulsed Doppler is also enabled then pulsed Doppler will remain the dominant mode and the thermal index change will be small.

Color Sector Depth

Deeper color sector depth may automatically decrease color frame rate or select a new color focal zone or color pulse length. the thermal index will change due to the combination of these effects. Generally, the thermal index will decrease with increased color sector depth. MI will correspond to the peak intensity of the dominant pulse type which is a color pulse. However, if pulsed Doppler is also enabled then pulsed Doppler will remain the dominant mode and the thermal index change will be small.

SCALE

Using the **SCALE** control to increase the color velocity range may increase the thermal index. The system may automatically adjust pulser voltage to stay below the system maximums. A decrease in pulser voltage will also decrease MI.

SEC WIDTH

A narrower 2D sector width in Color imaging will increase color frame rate. The thermal index will increase. MI will not change. If pulsed Doppler is also enabled, then pulsed Doppler will remain the dominant mode and the thermal index change will be small.

M-Mode and Doppler Controls

Sweep Speed

M-mode and Doppler sweep speed adjustments will not affect the thermal indices or MI.

Simultaneous and Update Methods

Use of combination modes affects both the thermal index and MI through the combination of pulse types. During simultaneous mode, the thermal index is additive. During auto-update and duplex, the thermal index will display the dominant pulse type. The displayed MI will be from the mode with the largest peak pressure.

Sample Volume Size

An increase in the Doppler sample volume size will increase the thermal index. MI is not affected. The system may decrease pulser voltage to maintain output below the system maximum. This decrease in pulser voltage would decrease MI.

Sample Volume Depth

When Doppler sample volume depth is increased the Doppler PRF may automatically decrease. A decrease in PRF will decrease the thermal index. The system may also automatically decrease the pulser voltage to remain below the system maximum. A decrease in pulser voltage will decrease MI.

Other

PULSED, CW, COLOR, PWR IMG, M MODE, COMP IMG, and 2D Imaging Controls

When a new imaging mode is selected, both the TI and MI may change to default settings. Each mode has a corresponding pulse repetition frequency and maximum intensity point. In combined or simultaneous modes, the thermal index is the sum of the contribution from the modes enabled and MI is the MI for the focal zone and mode with the largest derated intensity. The system will return to the previously selected state if a mode is turned off and then reselected.

Scanhead

Each scanhead model available has unique specifications for contact area, beam shape, and center frequency. Defaults will be initialized when you select a scanhead. ATL factory defaults vary with scanhead, clinical option, Tissue Specific preset, and selected mode. Defaults have been chosen below the FDA limits for intended use.

DEPTH

An increase in 2D depth will automatically decrease the 2D frame rate. This would decrease the TI. The system may also automatically choose a deeper 2D focal depth. A change of focal depth may change the MI. The MI displayed is that of the zone with the largest peak intensity.

Clinical Options and Tissue Specific Presets

Acoustic output defaults are set when you select a Tissue Specific preset. ATL factory defaults vary with scanhead, clinical option, Tissue Specific preset, and selected mode. Defaults have been chosen below the FDA limits for intended use.


Related Guidance Documents

For more information about ultrasonic bioeffects and related topics refer to the following:

- “Bioeffects and Safety of Diagnostic Ultrasound.” AIUM Report, January 28, 1993.
- “Bioeffects Considerations for the Safety of Diagnostic Ultrasound.” *Journal of Ultrasound in Medicine*, Vol. 7, No. 9 Supplement: September 1988.
- Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment. AIUM, NEMA, May 1998.
- Acoustic Output Labeling Standard for Diagnostic Ultrasound Equipment. AIUM, January 1998.
- Second Edition of the AIUM Output Display Standard Brochure, March 10, 1994. (A copy of this document is shipped with each system.)
- Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers. FDA. September 1997.
- Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, Revision 1. AIUM, NEMA, 1998.
- WFUMB. “Symposium on Safety of Ultrasound in Medicine: Conclusions and Recommendations on Thermal and Non-Thermal Mechanisms for Biological Effects of Ultrasound”. *“Ultrasound in Medicine and Biology,* Vol. 24, Supplement 1: 1998.

Acoustic Output and Measurement

Since the initial use of diagnostic ultrasound, the possible human biological effects (bioeffects) from ultrasound exposure have been studied by various scientific and medical institutions. In October 1987, the American Institute of Ultrasound in Medicine (AIUM) ratified a report prepared by its Bioeffects Committee “Bioeffects Considerations for the Safety of Diagnostic Ultrasound.” *Journal of Ultrasound in Medicine*, Vol. 7, No. 9 Supplement: September 1988, sometimes referred to as the Stowe Report, which reviewed available data on possible effects of ultrasound exposure. Another report “Bioeffects and Safety of Diagnostic Ultrasound,” dated January 28, 1993, provides more current information.

The acoustic output for this system has been measured and calculated in accordance with the “Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment” (AIUM, NEMA 1998), the “Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment” (Revision 1, AIUM, NEMA, 1998), and the September, 1997, FDA document “Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers.”

In Situ, Derated, and Water Value Intensities

All intensity parameters are measured in water. Since water does not absorb acoustic energy, these water measurements represent a worst case value. Biological tissue does absorb acoustic energy. The true value of the intensity at any point depends on the amount and type of tissue and the frequency of the ultrasound that passes through the tissue. The intensity value in the tissue, *in situ*, has been estimated by using the following formula:

$$In\ Situ \ = \ Water\ [e^{-(0.23alf)}]$$

where:	*In Situ*	=	*In Situ* Intensity Value
	Water	=	Water Value Intensity
	e	=	2.7183
	a	=	Attenuation Factor
	Tissue	=	a(dB/cm–MHz)
	Brain	=	.53
	Heart	=	.66
	Kidney	=	.79
	Liver	=	.43
	Muscle	=	.55
	l	=	Skin line to measurement depth (cm)
	f	=	Center frequency of the scanhead/system/mode combination (MHz)

Since the ultrasonic path during an examination is likely to pass through varying lengths and types of tissue, it is difficult to estimate the true *in situ* intensity. An attenuation factor of 0.3 is used for general reporting purposes; therefore, the *in situ* value which is commonly reported uses the formula:

$$In\ Situ\ (derated) \ = \ Water\ [e^{-(0.069lf)}]$$

Since this value is not the true *In Situ* intensity, the term “derated” is used.

Mathematical derating of water-based measurements, using the 0.3 dB/cm/MHz coefficient, may yield lower acoustic exposure values than would be measured in a homogenous 0.3 dB/cm/MHz tissue. This is true because non-linearly propagating acoustic energy waveforms experience more distortion and saturation in water than in tissue, where attenuation present all along the tissue path will dampen the build up of non-linear effects.

The maximum derated and the maximum water values do not always occur at the same operating conditions; therefore, the reported maximum water and derated values may not be related by the *In Situ* (derated) formula. For example: a multi-zone array scanhead that has maximum water value intensities in its deepest zone, but also has the smallest derating factor in that zone. The same scanhead may have its largest derated intensity in one of its shallowest focal zones.

Conclusions Regarding Tissue Models and Equipment Survey

Tissue models are necessary to estimate attenuation and acoustic exposure levels *In Situ* from measurements of acoustic output made in water. Presently, available models may be limited in their accuracy because of varying tissue paths during diagnostic ultrasound exposures and uncertainties in acoustical properties of soft tissues. No single tissue model is adequate for predicting exposures in all situations from measurements made in water, and continued improvement and verification of these models is necessary for making exposure assessments for specific applications.

A homogeneous tissue model with an attenuation coefficient of 0.3 dB/cm–MHz throughout the beam path is commonly assumed when estimating exposure levels. The model is conservative in that it overestimates the *in situ* acoustic exposure when the path between the transducer and the site of interest is composed entirely of soft tissue, because the attenuation coefficient of soft tissue is generally higher than 0.3 dB/cm–MHz. When the path contains significant amounts of fluid, as in many first and second-trimester pregnancies scanned transabdominally, this model may underestimate the *in situ* acoustical exposure. The amount of underestimation depends on each specific situation.

Fixed-path tissue models, in which soft tissue thickness is held constant, sometimes are used to estimate *In Situ* acoustical exposures when the beam path is longer than 3 cm and consists largely of fluid. When this model is used to estimate maximum exposure to the fetus during transabdominal scans, a value of 1 dB/MHz may be used during all trimesters.

Existing tissue models that are based on linear propagation may underestimate acoustical exposures when significant saturation due to non-linear distortion of beams in water is present during the output measurement.

The maximum acoustic output levels of diagnostic ultrasound devices extend over a broad range of values:

- A survey of 1990-equipment models yielded mechanical index (MI) values between 0.1 and 1 at their highest output settings. Maximum MI values of approximately 2 are known to occur for currently available equipment. Maximum MI values are similar for real-time 2D, M-mode, pulsed Doppler, and Color flow imaging.


- Computed estimates of upper limits to temperature elevations during transabdominal scans were obtained in a survey of 1988 and 1990 pulsed Doppler equipment. The vast majority of models yielded upper limits less than 1 degree C and 4 degrees C for exposures of first-trimester fetal tissue and second-trimester fetal bone, respectively. The largest values obtained were approximately 1.5 degrees C for first-trimester fetal tissue and 7 degrees C for second-trimester fetal bone. Estimated maximum temperature elevations given here are for a “fixed-path” tissue model and are for devices having I_{SPTA} values greater than 500 mW/cm^2. The temperature elevations for fetal bone and tissue were computed based on calculation procedures given in Sections 4.3.2.1–4.3.2.6 in “Bioeffects and Safety of Diagnostic Ultrasound (AIUM, 1993).”

Acoustic Output Tables

Acoustic output tables are found in *HDI 5000 Ultrasound System Acoustic Output Tables,* 4706-0027-XX. All table entries have been obtained at the same operating conditions that give rise to the maximum index value in the first column of the tables.

Acoustic Measurement Precision and Uncertainty

Measurement precision and uncertainty for power, pressure, intensity, and center frequency are shown in Table 7–1 and Table 7–2.

Table 7–1. Acoustic Measurement Precision

Note *Per Section 6.4 of the Output Display Standard, measurement precision on the following quantities is determined by making repeated measurements and stating the standard deviation as a percentage.*

Quantity	Precision (percentage standard deviation)
Pr is the un-derated and Pr.3 is the derated peak rarefactional pressure measured in MegaPascals.	Pr: 2.2% Pr.3: 5.4%
Wo is the ultrasonic power in milliWatts.	6.2%
f_c is the center frequency in MHz (NEMA UD–2 definition).	<1%
PII is the un-derated and PII.3 is the derated spatial-peak pulse intensity integral in Joules/cm^2.	PII: 3.2% PII.3: 3.2%

Table 7–2. Acoustic Measurement Uncertainty

Quantity	Measurement Uncertainty (percentage, 95% confidence value)
Pr is the un-derated and Pr.3 is the derated peak rarefactional pressure measured in MegaPascals.	Pr: ±13% Pr.3 ±15%
Wo is the ultrasonic power in milliWatts.	±19%
f_c is the center frequency in MHz (NEMA UD–2 definition).	±4.5%
PII is the un-derated and PII.3 is the derated spatial-peak pulse intensity integral in Joules/cm^2.	PII: +18% to –23% PII.3: +19% to –24%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P

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T

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W